

US3692016 (Prod: University of North Carolina at Chapel Hill)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:24:59

All time stamps listed in this document are displayed in GMT

US3692016

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

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[Participant ID](#)

US3692016

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

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US3692016

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:16:13

Generated On: 10 Jun 2021 09:24:59

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

US3692016

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 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 type="radio"/> Amendment 3 <input checked="" 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

US3692016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	REACTIVE AIRWAY DISEASE
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	ENVIRONMENTAL ALLERGIES (DOG HAIR, RAGWEED)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	ILIAC ARTERY ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	SLOW PROGRESSION OF ATHEROSCLEROSIS
Start date (dd MMM yyyy)	UN JUN 2019
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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3692016

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	FOLLICULITIS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:05 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:05
Height ( <i>xxx.x</i> )	185 cm
Weight ( <i>xxx.x</i> )	114.9 kg
BMI ( <i>xxx.x</i> )	33.57195 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:49:16

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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**

EXPOSURE TO LAB PERSONNEL  
DAILY, 30-60 MINUTES PER  
DAY SPENT IN THE LAB

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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

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:49:16

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<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>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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

What was the participant's randomization number? 109456

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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)	29 AUG 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

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)	29 AUG 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 12:14
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:44 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 11:44

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 AUG 2020
Collection time (00:00-23:59)	10:57 (24 HR)
Collection date and time (derived)	29 AUG 2020 10:57

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:02	29 AUG 2020 11:02
Nasopharyngeal Swab 2	No		

US3692016

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**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

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:04

PC Close Date & Time

29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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 96.4 °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	30 AUG 2020 09:05
PC Open Date & Time	29 AUG 2020 15:29
PC Close Date & Time	30 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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

96.1 °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

31 AUG 2020 06:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**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

97.0 °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

01 SEP 2020 05:24

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 05:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

02 SEP 2020 21:20

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**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

95.9 °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

04 SEP 2020 07:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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

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

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:18

PC Open Date & Time

29 AUG 2020 12:04

PC Close Date & Time

29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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

30 AUG 2020 09:05

PC Open Date & Time

29 AUG 2020 15:29

PC Close Date & Time

30 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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

31 AUG 2020 06:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**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

01 SEP 2020 05:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**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

02 SEP 2020 05:46

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**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

04 SEP 2020 07:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**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 ☐

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 12:18
PC Open Date & Time	29 AUG 2020 12:04
PC Close Date & Time	29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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 ☐

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

No ☒

Yes ☐

PC Time stamp	30 AUG 2020 09:06
PC Open Date & Time	29 AUG 2020 15:29
PC Close Date & Time	30 AUG 2020 11:59



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 06:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 05:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 05:46
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:21
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 07:52
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 09:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

CONCOMITANT MEDICATION  
LIST AND ADVERSE EVENT  
LIST UPDATED.

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

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)	23 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:18
Temperature (xxx.x)	36.6 C
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

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)	23 SEP 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:38
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

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.*

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 10:08

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

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:11



US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	23 SEP 2020 09:18
Nasopharyngeal Swab 2	No		

US3692016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**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

23 SEP 2020 10:40

PC Open Date & Time

23 SEP 2020 10:28

PC Close Date & Time

23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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	23 SEP 2020 19:37
PC Open Date & Time	23 SEP 2020 13:53
PC Close Date & Time	24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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

25 SEP 2020 04:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**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

97.0 °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

25 SEP 2020 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**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

97.0 °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

26 SEP 2020 16:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**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

97.0 °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

27 SEP 2020 19:56

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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

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

30 SEP 2020 07:26

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 10:40

PC Open Date & Time

23 SEP 2020 10:28

PC Close Date & Time

23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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

23 SEP 2020 19:37

PC Open Date & Time

23 SEP 2020 13:53

PC Close Date & Time

24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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

25 SEP 2020 04:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**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

25 SEP 2020 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**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

26 SEP 2020 16:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**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

27 SEP 2020 19:56

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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

30 SEP 2020 07:26

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**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 ☐

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:41
PC Open Date & Time	23 SEP 2020 10:28
PC Close Date & Time	23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**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 ☐

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 19:38
PC Open Date & Time	23 SEP 2020 13:53
PC Close Date & Time	24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 04:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 16:40
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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

100 of 2433

EAB) (1725)

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**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  
EAB) (1725)

102 of 2433

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 07:27
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments PARTICIPANT REPORTS NO  
HEALTH CHANGES. PLANS TO  
GET FLU VACCINE ON 10/15/20.  
*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PARTICIPANT REPORTS NO  
CHANGES SINCE LAST  
CONTACT BY STUDY.

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

ROSUVASTATIN CHANGED  
FROM QOD TO TWICE WEEKLY

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:16

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:51:56

Generated On: 10 Jun 2021 09:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:51:56

Generated On: 10 Jun 2021 09:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	8:03 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 8:03
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3692016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:51:56

Generated On: 10 Jun 2021 09:24:59

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.*

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	8:36 (24 HR)
Collection date and time (derived)	23 OCT 2020 8:36

US3692016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:49:17

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 NOV 2020 08:22:58
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2020 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 DEC 2020 13:49:20
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 17:59:38

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 12:38:53

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 16:43:15

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 11:05:24

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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 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	06 JAN 2021 13:26:19
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

11 JAN 2021 20:08:47

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 13:34:30

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

29 JAN 2021 20:26:29

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 12:00:38

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

11 FEB 2021 18:20:10

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 12:00:39

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

25 FEB 2021 02:20:38

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 05:52:02

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 06:04:48

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

15 MAR 2021 20:51:32

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

25 MAR 2021 18:00:38

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

30 MAR 2021 12:11:27

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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

05 APR 2021 20:13:08

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 12:01:14

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 09:59:11

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 08:37:26

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 264

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	21 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	12 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUL 2021 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

26 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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16 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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27 AUG 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

20 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

27 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 404

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

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

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	04 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 OCT 2021 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	11 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	18 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

15 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	06 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	13 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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[Patient Cloud Close Date & Time](#)

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31 DEC 2021 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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="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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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24 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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="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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 FEB 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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21 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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28 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	21 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAR 2022 23:59
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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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25 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 APR 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	11 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2022 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

25 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59



US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

15 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	12 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	10 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2022 23:59

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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

**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 ☐

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	24 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2022 23:59
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US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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"/>

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2022 23:59

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US3692016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:24:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 05:52:14

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

NO CHANGES TO HEALTH OR  
MEDICATIONS AT THIS TIME.

*If Contact Not Made, please provide Comments*

NEW CONSENT REVIEWED AND  
SIGNED.

US3692016

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3692016

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

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

Visit date (dd MMM yyyy)	17 MAR 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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US3692016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:16:13

Generated On: 10 Jun 2021 09:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:08 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:08
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3692016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

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.*

US3692016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

09:11 (24 HR)

Collection date and time (derived)

17 MAR 2021 09:11

US3692016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:26:37

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:26:37

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3692016**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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*

**US3692016**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3692016**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:24:59**

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"/>

**US3692016**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3692016

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

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

US3692016

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 19:17:44

Generated On: 10 Jun 2021 09:24:59

Date of updated informed consent ( <i>dd MMM yyyy</i> )	9 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	9 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3692016**

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

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 05 Mar 2021 20:57:51**

**Generated On: 10 Jun 2021 09:24:59**

Height	185 cm
Weight	110.9 kg
BMI (xxx.x)	32.40321

US3692016

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:57:51

Generated On: 10 Jun 2021 09:24:59

Height	185 cm
Weight	110.9 kg
BMI (xxx.x)	32.40321
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:01
Temperature (xxx.x)	35.0 C
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3692016

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:57:51

Generated On: 10 Jun 2021 09:24:59

Height	185 cm
Weight	110.9 kg
BMI (xxx.x)	32.40321
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:03
Temperature (xxx.x)	35.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

09 JAN 2021

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

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US3692016

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 11:31 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 11:31

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

US3692016

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 JAN 2021

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

09 JAN 2021 08:55

US3692016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 JAN 2021

Collection time (00:00 - 23:59)

09:00

Collection Date and Time (derived)

09 JAN 2021 09:00

US3692016

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

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



US3692016

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

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)	08 FEB 2021
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 08:28
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

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)	08 FEB 2021
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 09:34
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3692016

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 09:03 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 09:03

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

US3692016

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:57:51

Generated On: 10 Jun 2021 09:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3692016

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:57:51

Generated On: 10 Jun 2021 09:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3692016

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

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

Visit date (dd MMM yyyy)	17 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3692016

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:08 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:08
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3692016

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

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.*

US3692016

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:59:52

Generated On: 10 Jun 2021 09:24:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	17 MAR 2021 09:11

US3692016

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

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

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

AEID	USA-US123-2020-MRNA-1273-P30 1000001
Adverse event	ILIAC ARTERY ANEURYSM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	01 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	08 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 23:36:02

Generated On: 10 Jun 2021 09:24:59

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ADMITTED FOR ELECTIVE  
OPEN REPAIR OF 3.7CM RIGHT  
ILIAC ANEURYSM, WHICH WAS  
AN INCIDENTAL FINDING IN  
2017. REPAIR WENT WELL AND  
STAYED IN HOSPITAL  
POST-SURGERY FOR PAIN  
MANAGEMENT. DISCHARGED  
WITHOUT COMPLICATIONS ON  
08-NOVEMBER-2020.  
CONSISTENT WITH SAE  
REPORTING CRITERIA AS  
OUTLINED ON PAGE 74 OF  
PROTOCOL AMENDMENT 4,  
DUE TO INPATIENT  
HOSPITALIZATION.

---

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)	1

---

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

---

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

Yes ☒

No ☐

---

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

---

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication REACTIVE-AIRWAY DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2017	
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication ZETIA

Prophylaxis Yes ☒  
No ☐

Indication SECONDARY PREVENTION FOR  
CARDIOVASCULAR DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2017
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication SLOW PROGRESSION OF  
ATHEROSCLEROSIS

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 ☐

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US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication (BUDESONIDE) PULMICORT  
INHALER

Prophylaxis Yes ☐  
No ☒

Indication REACTIVE AIRWAY DISEASE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication GLUCOSAMINE - CHONDROITIN  
CAPSULE

Prophylaxis Yes ☐  
No ☒

Indication JOINT HEALTH

Dose per administration 1500/200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication GARLIC

Prophylaxis Yes ☐  
No ☒

Indication HEART HEALTH

Dose per administration UNKNOWN

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication TUMERIC CAPSULE

Prophylaxis Yes ☐  
No ☒

Indication JOINT HEALTH

Dose per administration 1350

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication MULTIVITAMIN FOR MEN

Prophylaxis Yes ☐  
No ☒

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication FISH OIL CAPSULES

Prophylaxis Yes ☐  
No ☒

Indication HEALTH PROMOTION

Dose per administration 1400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication GINGER

Prophylaxis Yes ☐  
No ☒

Indication HEART HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication CITRACAL (CALCIUM AND VITAMIN D3)

Prophylaxis Yes ☐  
No ☒

Indication BONE HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication COENZYME Q10

Prophylaxis Yes ☐  
No ☒

Indication HEART HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
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)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)	21 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HPERLIPIDEMIA

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

2X A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN (POST-BILATERAL ILIAC ANEURYSM REPAIR)

Dose per administration 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

2 TABLETS Q6N

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)		08 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)		31 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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication COLACE

Prophylaxis Yes ☐  
No ☒

Indication STOOL SOFTENER FOLLOWING  
ILIAC ARTERY ANEURYSM  
PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)	08 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)	08 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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication PAIN (POST BILATERAL ILIAC ANEURYSM REPAIR)

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

1 TABLET PRN/Q4 HOURS FOR  
UP TO 5 DAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)		08 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)		13 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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication SENOKOT

Prophylaxis Yes ☐  
No ☒

Indication STIMULANT LAXATIVE -  
FOLLOWING ILIAC ARTERY  
ANEURYSM PROCEDURE

Dose per administration 17.2

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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)	08 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)	08 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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication CIALIS

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

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

1-2 TABLETS PRN

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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 2010	
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication PREVIDENT 1.1%

Prophylaxis Yes ☒  
No ☐

Indication ORAL HYGIENE

Dose per administration 1

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

If dose unit is Other, specify ADMINISTRATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	ORAL TOOTHPASTE	
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication PREVENTIL

Prophylaxis Yes ☐  
No ☒

Indication REACTIVE AIRWAY  
DISEASE/ENVIRONMENTAL  
ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

PRN Q6 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2006	
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"/>

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

Name of Medication CLINDAMYCIN 1%

Prophylaxis Yes ☐  
No ☒

Indication FOLLICULITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Feb 2021 23:36:03

Generated On: 10 Jun 2021 09:24:59

	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"/>

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 NOV 2020	OPEN ILIAC ARTERY REPAIR	Medical History	

US3692016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:24:59

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

US3692016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:24:59

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 ☐

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

SAEID	USA-US123-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

SAEID	USA-US123-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 20:37
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.	True

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

SAEID	USA-US123-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

SAEID	USA-US123-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 13:56
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

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 23:36:04

Generated On: 10 Jun 2021 09:24:59

SAEID	USA-US123-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/NOV/2020 18:05
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

US3692016 (Prod: University of North Carolina at Chapel Hill)

**US3692016**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:24:59**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'US3692016'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:19:31

**US3692016**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	29 Aug 2020 14:49:51

**US3692016**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:19:32

US3692016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
Signature has been broken.	Maria Stetson (b) (4)	31 Mar 2021 12:39:23
User entered 'Home (Home)' reason for change: New Information	Maria Stetson (b) (4)	31 Mar 2021 12:39:23
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4)	29 Aug 2020 14:49:51

**US3692016**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'SCRN'	System	29 Aug 2020 14:49:51



US3692016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:19:33

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '55'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'YEARS'	System	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '55'	System	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Male (M)'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'I'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24



**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

**US3692016**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:24:59**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Mandy Tipton (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '25 Aug 2020'	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22



**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Aug 2020'	System	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2020'	System	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Amendment 3 (3)'	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:50:22

**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:19:32



**US3692016**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:24:59**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'I'	System	29 Aug 2020 14:50:59

**US3692016**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	29 Aug 2020 14:50:59

**US3692016**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:24:59**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:33
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:42:24

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchial hyperreactivity, LLT: Reactive airways disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
Data point term sent to Coder	System	01 Sep 2020 17:43:49
User entered 'reactive airway disease'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2000'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16



**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jan 2000'	System	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2000'	System	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:43:16

**US3692016**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:13:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:13:32
Data point term sent to Coder	System	01 Sep 2020 17:44:55
User entered 'environmental allergies (dog hair, ragweed)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03



**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jan 2017'	System	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2017'	System	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:44:03

**US3692016**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Peripheral aneurysms and dissections, PT: Peripheral artery aneurysm, LLT: Iliac artery aneurysm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:46:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:46:47
Data point term sent to Coder	System	01 Sep 2020 17:45:59
User entered 'iliac artery aneurysm'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:45:47



**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2016'	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jan 2016'	System	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2016'	System	01 Sep 2020 17:45:47

**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:45:47



**US3692016**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Atherosclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:22:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:22:31
Data point term sent to Coder	System	23 Oct 2020 23:14:18
User entered 'slow progression of athersclerosis'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un Jun 2019'	Kristi Kirkland (b) (4)	23 Oct 2020 23:14:12
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Kristi Kirkland (b) (4)	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jun 2019'	System	23 Oct 2020 23:14:12



**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2019'	System	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	23 Oct 2020 23:14:12

**US3692016**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:04:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:04:53
Data point term sent to Coder	System	17 Nov 2020 16:48:51
User entered 'Erectile Dysfunction'	Maria Stetson (b) (4)	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	(b) (4) Maria Stetson (b) (4)	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'I'	Maria Stetson (b) (4)	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Maria Stetson (b) (4)	17 Nov 2020 16:48:45



**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Maria Stetson (b) (4)	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 16:48:45

**US3692016**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Folliculitis, LLT: Folliculitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:22:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:22:49
Data point term sent to Coder	System	17 Nov 2020 20:21:59
User entered 'Folliculitis'	Maria Stetson (b) (4)	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'UN UNK 2005'	Maria Stetson (b) (4)	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Maria Stetson (b) (4)	17 Nov 2020 20:21:39



**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Maria Stetson (b) (4)	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Maria Stetson (b) (4)	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jan 2005'	System	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2005'	System	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 20:21:39

**US3692016**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:45:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:45:56
Data point term sent to Coder	System	04 Dec 2020 14:45:40
User entered 'Hypertension'	Maria Stetson (b) (4)	04 Dec 2020 14:44:45



**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'UN UNK 2019'	Maria Stetson (b) (4)	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Maria Stetson (b) (4)	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	04 Dec 2020 14:44:45
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	(b) (4) Maria Stetson (b) (4)	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Maria Stetson (b) (4)	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'Jan 2019'	System	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '2019'	System	04 Dec 2020 14:44:45

**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	04 Dec 2020 14:44:45



**US3692016**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered empty.	System	04 Dec 2020 14:44:45

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:33:49
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'Date is correct. Several screening assessments were completed on the day of entry.' (Site from System).	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 22:19:56
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 17:50:56
User entered '29 Aug 2020'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '10:05'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '29 Aug 2020 10:05'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '185' cm	(b) (4)	
	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
	(b) (4)	
DataPoint set to visible.	System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '114.9' kg	(b) (4) Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
DataPoint set to visible.	(b) (4) System	29 Aug 2020 14:50:59

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '33.57195'	System	01 Sep 2020 17:50:56
DataPoint set to visible.	System	29 Aug 2020 14:50:59



**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'kg/m2'	System	01 Sep 2020 17:50:56
DataPoint set to visible.	System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 09:01:35
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:03
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:34:06
User entered '36.6' C	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered 'Oral (Oral)'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:03
User entered '76'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'bpm'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:03
User entered '16'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'breaths/min'	System	01 Sep 2020 17:50:56



US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:03
User entered '148'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:03
User entered '97'	Mandy Tipton (b) (4)	01 Sep 2020 17:50:56
	(b) (4)	

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	01 Sep 2020 17:50:56

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15

**US3692016**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15

US3692016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Maria Stetson (b) (4)	01 Oct 2020 15:37:36
User entered 'No (N)'	(b) (4)	
	Abigail Riddick (b) (4)	01 Sep 2020 17:51:24
	(b) (4)	

US3692016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:37:36
User entered empty.	Maria Stetson (b) (4)	01 Oct 2020 15:37:36
	(b) (4)	
	Abigail Riddick (b) (4)	01 Sep 2020 17:51:24
	(b) (4)	



US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	(b) (4) Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39



US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

**US3692016**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:24:59**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'exposure to lab personnel daily, 30-60 minutes per day spent in the lab'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

**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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39



US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	(b) (4) Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'I'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

**US3692016**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:24:59**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	29 Aug 2020 14:52:56

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Mandy Tipton (b) (4)	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4)	29 Aug 2020 14:52:56



**US3692016**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'VISIT1'	System	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:45:36

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '109456'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:45:36

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:45:36

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:24:59**

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)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:59

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)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:53:27

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:53:27

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:53:27



**US3692016**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:24:59**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:59

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:15:05
Query 'Per CDM: This field requires a Yes or No response. Please complete. answered with 'Updated.' (Site from DM).	Erin Cardot (b) (4) (b) (4)	10 Dec 2020 17:03:23
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	10 Dec 2020 17:03:17
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 19:25:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:27:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:27:49

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Mandy Tipton (b) (4)	01 Sep 2020 18:10:57
	(b) (4)	

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Mandy Tipton (b) (4)	01 Sep 2020 18:10:57
	(b) (4)	

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Pre-Dose (PREDOSE)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57



US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '10:05'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '29 Aug 2020 10:05'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '36.6' C	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Oral (Oral)'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '76'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'bpm'	System	01 Sep 2020 18:10:57



US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '16'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'breaths/min'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '148'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '97'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Mandy Tipton (b) (4)	01 Sep 2020 18:10:57
	(b) (4)	



US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Post-Dose (POSTDOSE)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '12:14'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '29 Aug 2020 12:14'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '36.4' C	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Oral (Oral)'	(b) (4) Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57



US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '63'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'bpm'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '16'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'breaths/min'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '141'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '99'	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	01 Sep 2020 18:10:57



US3692016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:12:42

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Abigail Riddick (b) (4)	01 Sep 2020 18:12:42

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '11:44'	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09



**US3692016**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '29 Aug 2020 11:44'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'ONCE'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	02 Sep 2020 12:17:37

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '29 Aug 2020'	Mandy Tipton (b) (4)	02 Sep 2020 12:17:37

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '10:57'	Mandy Tipton (b) (4)	02 Sep 2020 12:17:37

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '29 Aug 2020 10:57'	System	02 Sep 2020 12:17:37



US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 12:17:48
System	System	02 Sep 2020 12:17:48
User entered '29 Aug 2020' reason for change: Data Entry Error	Mandy Tipton (b) (4)	02 Sep 2020 12:17:48
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	02 Sep 2020 12:17:17
	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17
	(b) (4)	

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '11:02'	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '29 Aug 2020 11:02'	System	02 Sep 2020 12:17:48
User entered empty.	System	02 Sep 2020 12:17:17

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 12:17:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:17:52
User entered 'No (N)' reason for change: Data Entry Error	Mandy Tipton (b) (4)	02 Sep 2020 12:17:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 12:17:17
User entered empty.	System	02 Sep 2020 12:17:17
	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17
	(b) (4)	

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17



**US3692016**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered empty.	System	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	02 Sep 2020 12:16:44

**US3692016**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	02 Sep 2020 12:16:44

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:16:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28' User entered 'Yes (Y)'	System	29 Aug 2020 16:17:50
	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28' User entered '97.5'	System	29 Aug 2020 16:17:50
	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28'	System	29 Aug 2020 16:17:50
User entered 'No (N)'	System	29 Aug 2020 16:17:50

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28' User entered '29 Aug 2020 12:17'	System	29 Aug 2020 16:17:50
	System	29 Aug 2020 16:17:50



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2' User entered 'Yes (Y)'	System	30 Aug 2020 13:06:35
	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2' User entered '96.4'	System	30 Aug 2020 13:06:35
	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered 'No (N)'	System	30 Aug 2020 13:06:35

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered '30 Aug 2020 09:05'	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:02:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c' User entered 'Yes (Y)'	System	31 Aug 2020 10:03:09
	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:02:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c' User entered '96.1'	System	31 Aug 2020 10:03:09
	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c' User entered 'No (N)'	System	31 Aug 2020 10:03:09
	System	31 Aug 2020 10:03:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c' User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:09
	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:23:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff' User entered 'Yes (Y)'	System	01 Sep 2020 09:24:49
	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff' User entered '97.0'	System	01 Sep 2020 09:24:49
	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff' User entered 'No (N)'	System	01 Sep 2020 09:24:49
	System	01 Sep 2020 09:24:49

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff' User entered '01 Sep 2020 05:24'	System	01 Sep 2020 09:24:49
	System	01 Sep 2020 09:24:49

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168' User entered 'Yes (Y)'	System	02 Sep 2020 09:45:51
	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168' User entered '96.2'	System	02 Sep 2020 09:45:51
	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168' User entered 'No (N)'	System	02 Sep 2020 09:45:51
	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168' User entered '02 Sep 2020 05:45'	System	02 Sep 2020 09:45:51
	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281' User entered 'Yes (Y)'	System	03 Sep 2020 01:21:02
	System	03 Sep 2020 01:21:02



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281' User entered '98.1'	System	03 Sep 2020 01:21:02
	System	03 Sep 2020 01:21:02

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281' User entered 'No (N)'	System	03 Sep 2020 01:21:02
	System	03 Sep 2020 01:21:02

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281' User entered '02 Sep 2020 21:20'	System	03 Sep 2020 01:21:02
	System	03 Sep 2020 01:21:02

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd' User entered 'Yes (Y)'	System	04 Sep 2020 11:51:38
	System	04 Sep 2020 11:51:38

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd' User entered '95.9'	System	04 Sep 2020 11:51:38
	System	04 Sep 2020 11:51:38



US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd' User entered 'No (N)'	System	04 Sep 2020 11:51:38
	System	04 Sep 2020 11:51:38

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd' User entered '04 Sep 2020 07:51'	System	04 Sep 2020 11:51:38
	System	04 Sep 2020 11:51:38

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a' User entered 'Yes (Y)'	System	05 Sep 2020 13:53:16
	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a' User entered '97.0'	System	05 Sep 2020 13:53:16
	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a' User entered 'No (N)'	System	05 Sep 2020 13:53:16
	System	05 Sep 2020 13:53:16



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:16
	System	05 Sep 2020 13:53:16

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6' User entered 'None (1)'	System	29 Aug 2020 16:18:20
	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6' User entered 'No (N)'	System	29 Aug 2020 16:18:20
	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6' User entered 'No (N)'	System	29 Aug 2020 16:18:20
	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered 'None (1)'	System	29 Aug 2020 16:18:20



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6' User entered '29 Aug 2020 12:18'	System	29 Aug 2020 16:18:20
	System	29 Aug 2020 16:18:20

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'None (1)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'No (N)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'No (N)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'None (1)'	System	30 Aug 2020 13:06:38



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered '30 Aug 2020 09:05'	System	30 Aug 2020 13:06:38

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'None (1)'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965' User entered 'No (N)'	System	31 Aug 2020 10:03:30
	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965' User entered 'No (N)'	System	31 Aug 2020 10:03:30
	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'None (1)'	System	31 Aug 2020 10:03:30



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965' User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:30
	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c' User entered 'None (1)'	System	01 Sep 2020 09:25:05
	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c' User entered 'No (N)'	System	01 Sep 2020 09:25:05
	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c' User entered 'No (N)'	System	01 Sep 2020 09:25:05
	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c' User entered 'None (1)'	System	01 Sep 2020 09:25:05
	System	01 Sep 2020 09:25:05



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c' User entered '01 Sep 2020 05:25'	System	01 Sep 2020 09:25:05
	System	01 Sep 2020 09:25:05

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1' User entered 'None (1)'	System	02 Sep 2020 09:46:04
	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1' User entered 'No (N)'	System	02 Sep 2020 09:46:04
	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1' User entered 'No (N)'	System	02 Sep 2020 09:46:04
	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1' User entered 'None (1)'	System	02 Sep 2020 09:46:04
	System	02 Sep 2020 09:46:04



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1' User entered '02 Sep 2020 05:46'	System	02 Sep 2020 09:46:04
	System	02 Sep 2020 09:46:04

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered 'None (1)'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered 'No (N)'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:06', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered 'No (N)'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered 'None (1)'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14



US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:40', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered 'None (1)'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d' User entered 'No (N)'	System	04 Sep 2020 11:51:57
	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d' User entered 'No (N)'	System	04 Sep 2020 11:51:57
	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d' User entered 'None (1)'	System	04 Sep 2020 11:51:57
	System	04 Sep 2020 11:51:57



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d' User entered '04 Sep 2020 07:51'	System	04 Sep 2020 11:51:57
	System	04 Sep 2020 11:51:57

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered 'None (1)'	System	05 Sep 2020 13:53:32
	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered 'No (N)'	System	05 Sep 2020 13:53:32
	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered 'No (N)'	System	05 Sep 2020 13:53:32
	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered 'None (1)'	System	05 Sep 2020 13:53:32
	System	05 Sep 2020 13:53:32



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:32
	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0' User entered 'None (0)'	System	29 Aug 2020 16:18:49
	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0' User entered 'None (0)'	System	29 Aug 2020 16:18:49
	System	29 Aug 2020 16:18:49



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0' User entered 'None (0)'	System	29 Aug 2020 16:18:49
	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'No (N)'	System	29 Aug 2020 16:18:49

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0' User entered '29 Aug 2020 12:18'	System	29 Aug 2020 16:18:49
	System	29 Aug 2020 16:18:49

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered 'None (0)'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'No (N)'	System	30 Aug 2020 13:06:41

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0' User entered '30 Aug 2020 09:06'	System	30 Aug 2020 13:06:41
	System	30 Aug 2020 13:06:41

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'None (0)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered 'No (N)'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3' User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:52
	System	31 Aug 2020 10:03:52

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'No (N)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:23', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered '01 Sep 2020 05:25'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:14', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:24', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'None (0)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered 'No (N)'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21' User entered '02 Sep 2020 05:46'	System	02 Sep 2020 09:46:34
	System	02 Sep 2020 09:46:34



**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:20', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:27', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'No (N)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:06', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'No (N)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered '04 Sep 2020 07:52'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'None (0)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered 'No (N)'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53



US3692016

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:11
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

**US3692016**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	09 Sep 2020 20:28:07

**US3692016**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '07 Sep 2020'	Mandy Tipton (b) (4)	09 Sep 2020 20:28:07

**US3692016**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	Mandy Tipton (b) (4)	09 Sep 2020 20:28:07

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	09 Sep 2020 20:28:07

**US3692016**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	09 Sep 2020 20:28:14



**US3692016**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	09 Sep 2020 20:28:14

**US3692016**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	14 Sep 2020 23:29:48

**US3692016**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '14 Sep 2020'	Kristi Kirkland (b) (4)	14 Sep 2020 23:29:48

**US3692016**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	Kristi Kirkland (b) (4)	14 Sep 2020 23:29:48

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	(b) (4) Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:48

**US3692016**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	14 Sep 2020 23:29:52

**US3692016**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	14 Sep 2020 23:29:52

**US3692016**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23



**US3692016**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '21 Sep 2020'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Concomitant medication list and adverse event list updated.' reason for change: Data Entry Error	Maria Stetson (b) (4)	01 Oct 2020 18:13:20
User entered empty.	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23

US3692016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:27

**US3692016**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	21 Sep 2020 18:25:27

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:02

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:02



**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'VISIT2'	System	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Pre-Dose (PREDOSE)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '08:18'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Sep 2020 08:18'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '36.6' C	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Oral (Oral)'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01



**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '75'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'bpm'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '18'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'breaths/min'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '120'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '78'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01



US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Post-Dose (POSTDOSE)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '10:38'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Sep 2020 10:38'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '36.4' C	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Oral (Oral)'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01



**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '70'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'bpm'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '20'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'breaths/min'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '131'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '85'	Mandy Tipton (b) (4)	23 Sep 2020 14:59:01



US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)' reason for change: Data Entry Error	Mandy Tipton (b) (4)	23 Sep 2020 14:54:33
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:14

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	23 Sep 2020 14:54:33
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:14

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34



US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '10:08'	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Sep 2020 10:08'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'ONCE'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:56:10

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:56:10

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '09:11'	Mandy Tipton (b) (4)	23 Sep 2020 14:56:10



**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Sep 2020 09:11'	System	23 Sep 2020 14:56:10

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:24:59**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '09:18'	Mandy Tipton (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Sep 2020 09:18'	System	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'No (N)'	Mandy Tipton (b) (4)	23 Sep 2020 14:57:05



**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered empty.	Mandy Tipton (b) (4)	23 Sep 2020 14:57:05

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered empty.	System	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:26:46

**US3692016**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	23 Sep 2020 14:26:46

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b' User entered 'Yes (Y)'	System	23 Sep 2020 14:40:03
	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b' User entered '97.5'	System	23 Sep 2020 14:40:03
	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b' User entered 'No (N)'	System	23 Sep 2020 14:40:03
	System	23 Sep 2020 14:40:03



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b' User entered '23 Sep 2020 10:40'	System	23 Sep 2020 14:40:03
	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered 'Yes (Y)'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered '97.9'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered 'No (N)'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered '23 Sep 2020 19:37'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4' User entered 'Yes (Y)'	System	25 Sep 2020 08:58:22
	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4' User entered '97.0'	System	25 Sep 2020 08:58:22
	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4' User entered 'No (N)'	System	25 Sep 2020 08:58:22
	System	25 Sep 2020 08:58:22

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4' User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:58:22
	System	25 Sep 2020 08:58:22

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffea82ea04' User entered 'Yes (Y)'	System	26 Sep 2020 00:04:47
	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffea82ea04' User entered '97.0'	System	26 Sep 2020 00:04:47
	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffea82ea04' User entered 'No (N)'	System	26 Sep 2020 00:04:47
	System	26 Sep 2020 00:04:47

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffea82ea04' User entered '25 Sep 2020 20:04'	System	26 Sep 2020 00:04:47
	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b' User entered 'Yes (Y)'	System	26 Sep 2020 20:40:23
	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b' User entered '97.0'	System	26 Sep 2020 20:40:23
	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b'	System	26 Sep 2020 20:40:23
User entered 'No (N)'	System	26 Sep 2020 20:40:23

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b' User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:23
	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered 'Yes (Y)'	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652' User entered '97.0'	System	27 Sep 2020 23:56:42
	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered 'No (N)'	System	27 Sep 2020 23:56:42

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered '27 Sep 2020 19:56'	System	27 Sep 2020 23:56:42

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:24:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered 'Yes (Y)'	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60' User entered '97.0'	System	30 Sep 2020 11:26:33
	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered 'No (N)'	System	30 Sep 2020 11:26:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60' User entered '30 Sep 2020 07:26'	System	30 Sep 2020 11:26:33
	System	30 Sep 2020 11:26:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'None (1)'	System	23 Sep 2020 14:40:39



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b' User entered 'No (N)'	System	23 Sep 2020 14:40:39
	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b' User entered 'No (N)'	System	23 Sep 2020 14:40:39
	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'None (1)'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b' User entered '23 Sep 2020 10:40'	System	23 Sep 2020 14:40:39
	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0' User entered 'None (1)'	System	23 Sep 2020 23:38:04
	System	23 Sep 2020 23:38:04



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0' User entered 'No (N)'	System	23 Sep 2020 23:38:04
	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0' User entered 'No (N)'	System	23 Sep 2020 23:38:04
	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0' User entered 'None (1)'	System	23 Sep 2020 23:38:04
	System	23 Sep 2020 23:38:04

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0' User entered '23 Sep 2020 19:37'	System	23 Sep 2020 23:38:04
	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:23', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6' User entered 'None (1)'	System	25 Sep 2020 08:58:38
	System	25 Sep 2020 08:58:38



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6' User entered 'No (N)'	System	25 Sep 2020 08:58:38
	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6' User entered 'No (N)'	System	25 Sep 2020 08:58:38
	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6' User entered 'None (1)'	System	25 Sep 2020 08:58:38
	System	25 Sep 2020 08:58:38

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6' User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:58:38
	System	25 Sep 2020 08:58:38

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'None (1)'	System	26 Sep 2020 00:05:02



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'No (N)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'No (N)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33' User entered 'None (1)'	System	26 Sep 2020 00:05:02
	System	26 Sep 2020 00:05:02

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33' User entered '25 Sep 2020 20:04'	System	26 Sep 2020 00:05:02
	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a' User entered 'None (1)'	System	26 Sep 2020 20:40:37
	System	26 Sep 2020 20:40:37



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:27', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a' User entered 'No (N)'	System	26 Sep 2020 20:40:37
	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a' User entered 'No (N)'	System	26 Sep 2020 20:40:37
	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a' User entered 'None (1)'	System	26 Sep 2020 20:40:37
	System	26 Sep 2020 20:40:37

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:34', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a' User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:37
	System	26 Sep 2020 20:40:37

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered 'None (1)'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered 'No (N)'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered 'No (N)'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered 'None (1)'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered '27 Sep 2020 19:56'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185' User entered 'None (1)'	System	30 Sep 2020 11:26:54
	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185' User entered 'No (N)'	System	30 Sep 2020 11:26:54
	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185' User entered 'No (N)'	System	30 Sep 2020 11:26:54
	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185' User entered 'None (1)'	System	30 Sep 2020 11:26:54
	System	30 Sep 2020 11:26:54

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185' User entered '30 Sep 2020 07:26'	System	30 Sep 2020 11:26:54
	System	30 Sep 2020 11:26:54

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'None (0)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered 'No (N)'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:41:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c' User entered '23 Sep 2020 10:41'	System	23 Sep 2020 14:41:02
	System	23 Sep 2020 14:41:02

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:14', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'None (0)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:20', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered 'No (N)'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118' User entered '23 Sep 2020 19:38'	System	23 Sep 2020 23:38:25
	System	23 Sep 2020 23:38:25

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'None (0)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered 'No (N)'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c' User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:59:01
	System	25 Sep 2020 08:59:01

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'None (0)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered 'No (N)'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504' User entered '25 Sep 2020 20:05'	System	26 Sep 2020 00:05:20
	System	26 Sep 2020 00:05:20

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'None (0)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered 'No (N)'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1' User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:54
	System	26 Sep 2020 20:40:54

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'No (N)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered '27 Sep 2020 19:57'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33



**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15



US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'No (N)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered '30 Sep 2020 07:27'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

**US3692016**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:24:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34



**US3692016**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00

**US3692016**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '30 Sep 2020'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00

**US3692016**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'participant reports no health changes. plans to get flu vaccine on 10/15/20.' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Abigail Riddick (b) (4)	09 Oct 2020 16:52:11
	(b) (4)	
	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00
	(b) (4)	

**US3692016**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:04

**US3692016**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	30 Sep 2020 13:56:04

**US3692016**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Patti Vasquez (b) (4)	07 Oct 2020 17:44:21

**US3692016**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '07 Oct 2020'	Patti Vasquez (b) (4)	07 Oct 2020 17:44:21



**US3692016**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4)	07 Oct 2020 17:44:21

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'participant reports no changes since last contact by study.' reason for change: Data Entry Error	(b) (4)	
	Abigail Riddick (b) (4)	09 Oct 2020 16:52:52
User entered empty.	(b) (4)	
	Patti Vasquez (b) (4)	07 Oct 2020 17:44:21
	(b) (4)	

US3692016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Patti Vasquez (b) (4)	07 Oct 2020 17:44:27

**US3692016**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	07 Oct 2020 17:44:27

**US3692016**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:01:51

**US3692016**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:01:51

**US3692016**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:01:51

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Rosuvastatin changed from QOD to twice weekly'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:01:51



**US3692016**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:01:56

**US3692016**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	15 Oct 2020 21:01:56

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:14

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '23 Oct 2020'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered 'Clinic (Clinic)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:14

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'VISIT3'	System	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '23 Oct 2020'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45



**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '8:03'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Oct 2020 8:03'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '36.6' C	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered 'Oral (Oral)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '74'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'bpm'	System	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '16'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45



**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'breaths/min'	System	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '119'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered '69'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'mmHg'	System	23 Oct 2020 23:19:45

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered 'No (N)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:49



**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:51:56
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:19:49

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:20:05

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '23 Oct 2020'	Kristi Kirkland (b) (4)	23 Oct 2020 23:20:05

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered '8:36'	Kristi Kirkland (b) (4)	23 Oct 2020 23:20:05

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered '23 Oct 2020 8:36'	System	23 Oct 2020 23:20:05

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:49:17
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:20:10

**US3692016**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	23 Oct 2020 23:20:10

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 64'	System	29 Aug 2020 15:50:09



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Have you been exposed to someone with 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 71'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:53:36
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 78'	System	29 Aug 2020 15:50:09



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'Yes (Y)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

Have you been exposed to someone with 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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'No (N)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'No (N)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:59

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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'Yes (Y)'	System	12 Nov 2020 13:23:14

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Please 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 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 13:23:14

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352' User entered '12 Nov 2020 08:22:58'	System	12 Nov 2020 13:23:14
	System	12 Nov 2020 13:23:14

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 15:50:09

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:19:33
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 15:50:09



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-02T13:49:06', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e88920a0-28ba-43f5-922e-94c270dd9309' User entered 'No (N)'	System	02 Dec 2020 18:49:22
	System	02 Dec 2020 18:49:22

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-02T13:49:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e88920a0-28ba-43f5-922e-94c270dd9309' User entered 'No (N)'	System	02 Dec 2020 18:49:22
	System	02 Dec 2020 18:49:22

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-02T13:49:20', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e88920a0-28ba-43f5-922e-94c270dd9309' User entered '02 Dec 2020 13:49:20'	System	02 Dec 2020 18:49:22
	System	02 Dec 2020 18:49:22

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-10T17:59:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94c38fae-7430-4ad6-a3fd-062cf2e3bccf' User entered 'No (N)'	System	10 Dec 2020 22:59:40
	System	10 Dec 2020 22:59:40

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-10T17:59:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94c38fae-7430-4ad6-a3fd-062cf2e3bccf' User entered 'No (N)'	System	10 Dec 2020 22:59:40
	System	10 Dec 2020 22:59:40

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-10T17:59:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94c38fae-7430-4ad6-a3fd-062cf2e3bccf' User entered '10 Dec 2020 17:59:38'	System	10 Dec 2020 22:59:40
	System	10 Dec 2020 22:59:40

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:53:36



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-16T12:38:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3bb1c403-3a66-4a75-8398-01806b877be2' User entered 'No (N)'	System	16 Dec 2020 17:38:56

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-16T12:38:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3bb1c403-3a66-4a75-8398-01806b877be2' User entered 'No (N)'	System	16 Dec 2020 17:38:56
	System	16 Dec 2020 17:38:56

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-16T12:38:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3bb1c403-3a66-4a75-8398-01806b877be2' User entered '16 Dec 2020 12:38:53'	System	16 Dec 2020 17:38:56
	System	16 Dec 2020 17:38:56

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-22T16:43:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '13589920-8583-48a1-ae15-7d2f45ac82ab' User entered 'No (N)'	System	22 Dec 2020 21:43:21
	System	22 Dec 2020 21:43:21

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-22T16:43:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '13589920-8583-48a1-ae15-7d2f45ac82ab' User entered 'No (N)'	System	22 Dec 2020 21:43:21



**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-22T16:43:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '13589920-8583-48a1-ae15-7d2f45ac82ab' User entered '22 Dec 2020 16:43:15'	System	22 Dec 2020 21:43:21
	System	22 Dec 2020 21:43:21

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:53:36

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-31T11:05:14', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9942161d-a423-4cb3-b9c2-2c2fc6c85888' User entered 'No (N)'	System	31 Dec 2020 16:05:30
	System	31 Dec 2020 16:05:30

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-31T11:05:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9942161d-a423-4cb3-b9c2-2c2fc6c85888' User entered 'No (N)'	System	31 Dec 2020 16:05:30
	System	31 Dec 2020 16:05:30

**US3692016**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-12-31T11:05:24', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9942161d-a423-4cb3-b9c2-2c2fc6c85888' User entered '31 Dec 2020 11:05:24'	System	31 Dec 2020 16:05:30
	System	31 Dec 2020 16:05:30

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-06T13:26:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4bb55b83-de1a-47d4-9a8f-d30d2fd56b89' User entered 'No (N)'	System	06 Jan 2021 18:26:24
	System	06 Jan 2021 18:26:24

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-06T13:26:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4bb55b83-de1a-47d4-9a8f-d30d2fd56b89' User entered 'No (N)'	System	06 Jan 2021 18:26:24
	System	06 Jan 2021 18:26:24

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-06T13:26:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4bb55b83-de1a-47d4-9a8f-d30d2fd56b89' User entered '06 Jan 2021 13:26:19'	System	06 Jan 2021 18:26:24
	System	06 Jan 2021 18:26:24

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-11T20:08:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8f21fc98-1da6-4a7c-af39-78b3d742533a' User entered 'No (N)'	System	12 Jan 2021 01:08:51
	System	12 Jan 2021 01:08:51

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-11T20:08:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8f21fc98-1da6-4a7c-af39-78b3d742533a' User entered 'No (N)'	System	12 Jan 2021 01:08:51
	System	12 Jan 2021 01:08:51

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-11T20:08:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8f21fc98-1da6-4a7c-af39-78b3d742533a' User entered '11 Jan 2021 20:08:47'	System	12 Jan 2021 01:08:51
	System	12 Jan 2021 01:08:51

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-18T13:34:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a9f97836-1a69-4300-ab11-abecdf7d5914' User entered 'No (N)'	System	18 Jan 2021 18:34:34
	System	18 Jan 2021 18:34:34

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-18T13:34:27', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a9f97836-1a69-4300-ab11-abecdf7d5914' User entered 'No (N)'	System	18 Jan 2021 18:34:34



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-18T13:34:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a9f97836-1a69-4300-ab11-abecdf7d5914' User entered '18 Jan 2021 13:34:30'	System	18 Jan 2021 18:34:34
	System	18 Jan 2021 18:34:34

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-29T20:26:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8e2e8568-6224-4aad-b318-b81cd4b3db0e' User entered 'No (N)'	System	30 Jan 2021 01:26:37
	System	30 Jan 2021 01:26:37

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-29T20:26:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8e2e8568-6224-4aad-b318-b81cd4b3db0e' User entered 'No (N)'	System	30 Jan 2021 01:26:37

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-01-29T20:26:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8e2e8568-6224-4aad-b318-b81cd4b3db0e' User entered '29 Jan 2021 20:26:29'	System	30 Jan 2021 01:26:37

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-05T12:00:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f343ac9f-8fd7-4a44-964a-cf08d42d2576' User entered 'No (N)'	System	05 Feb 2021 17:02:27
	System	05 Feb 2021 17:02:27

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-05T12:00:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f343ac9f-8fd7-4a44-964a-cf08d42d2576'	System	05 Feb 2021 17:02:27
User entered 'No (N)'	System	05 Feb 2021 17:02:27

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-05T12:00:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f343ac9f-8fd7-4a44-964a-cf08d42d2576' User entered '05 Feb 2021 12:00:38'	System	05 Feb 2021 17:02:27
	System	05 Feb 2021 17:02:27

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-11T18:19:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3d97a31d-19ea-41a2-a8db-4f82896bc5e6' User entered 'No (N)'	System	11 Feb 2021 23:22:44
	System	11 Feb 2021 23:22:44

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-11T18:20:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3d97a31d-19ea-41a2-a8db-4f82896bc5e6' User entered 'No (N)'	System	11 Feb 2021 23:22:44
	System	11 Feb 2021 23:22:44

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-11T18:20:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3d97a31d-19ea-41a2-a8db-4f82896bc5e6' User entered '11 Feb 2021 18:20:10'	System	11 Feb 2021 23:22:44
	System	11 Feb 2021 23:22:44

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-17T12:00:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ef4f08ae-bce0-41d8-997e-ea464edde12a' User entered 'No (N)'	System	17 Feb 2021 17:02:53
	System	17 Feb 2021 17:02:53

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-17T12:00:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ef4f08ae-bce0-41d8-997e-ea464edde12a' User entered 'No (N)'	System	17 Feb 2021 17:02:53



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-17T12:00:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ef4f08ae-bce0-41d8-997e-ea464edde12a' User entered '17 Feb 2021 12:00:39'	System	17 Feb 2021 17:02:53

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-24T21:20:30-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '71f7219d-167e-47fc-a984-eae5bdb755ff' User entered 'No (N)'	System	25 Feb 2021 02:31:50
	System	25 Feb 2021 02:31:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-24T21:20:35-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '71f7219d-167e-47fc-a984-eae5bdb755ff' User entered 'No (N)'	System	25 Feb 2021 02:31:50
	System	25 Feb 2021 02:31:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-02-24T21:20:38-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '71f7219d-167e-47fc-a984-eae5bdb755ff' User entered '25 Feb 2021 02:20:38'	System	25 Feb 2021 02:31:50
	System	25 Feb 2021 02:31:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-02T05:51:56-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'addac309-99b5-43f9-937a-6d39a4dbb7d7'	System	02 Mar 2021 10:52:05
User entered 'No (N)'	System	02 Mar 2021 10:52:05

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-02T05:52:00-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'addac309-99b5-43f9-937a-6d39a4dbb7d7'	System	02 Mar 2021 10:52:05
User entered 'No (N)'	System	02 Mar 2021 10:52:05

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-02T05:52:02-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'addac309-99b5-43f9-937a-6d39a4dbb7d7'	System	02 Mar 2021 10:52:05
User entered '02 Mar 2021 05:52:02'	System	02 Mar 2021 10:52:05

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-08T06:04:40-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'cb1f53b3-b5f7-44b3-8c19-232980662010'	System	08 Mar 2021 11:04:50
User entered 'No (N)'	System	08 Mar 2021 11:04:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-08T06:04:45-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'cb1f53b3-b5f7-44b3-8c19-232980662010'	System	08 Mar 2021 11:04:50
User entered 'No (N)'	System	08 Mar 2021 11:04:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-08T06:04:48-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'cb1f53b3-b5f7-44b3-8c19-232980662010' User entered '08 Mar 2021 06:04:48'	System	08 Mar 2021 11:04:50
	System	08 Mar 2021 11:04:50

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-15T20:51:25-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6e1438ad-c748-44d9-8527-654b89245b86'	System	16 Mar 2021 00:51:39
User entered 'No (N)'	System	16 Mar 2021 00:51:39

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-15T20:51:29-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6e1438ad-c748-44d9-8527-654b89245b86'	System	16 Mar 2021 00:51:39
User entered 'No (N)'	System	16 Mar 2021 00:51:39



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-15T20:51:32-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6e1438ad-c748-44d9-8527-654b89245b86' User entered '15 Mar 2021 20:51:32'	System	16 Mar 2021 00:51:39

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-25T17:59:31-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd682e42a-f5b2-4850-9c74-e00af51e146c'	System	25 Mar 2021 22:01:53
User entered 'No (N)'	System	25 Mar 2021 22:01:53

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-25T18:00:31-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd682e42a-f5b2-4850-9c74-e00af51e146c'	System	25 Mar 2021 22:01:53
User entered 'No (N)'	System	25 Mar 2021 22:01:53

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-25T18:00:38-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd682e42a-f5b2-4850-9c74-e00af51e146c'	System	25 Mar 2021 22:01:53
User entered '25 Mar 2021 18:00:38'	System	25 Mar 2021 22:01:53

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-30T12:11:22-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3312b156-8948-40ef-a8cf-89130b7514b5'	System	30 Mar 2021 16:16:19
User entered 'No (N)'	System	30 Mar 2021 16:16:19

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-30T12:11:25-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3312b156-8948-40ef-a8cf-89130b7514b5'	System	30 Mar 2021 16:16:19
User entered 'No (N)'	System	30 Mar 2021 16:16:19

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-30T12:11:27-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3312b156-8948-40ef-a8cf-89130b7514b5' User entered '30 Mar 2021 12:11:27'	System	30 Mar 2021 16:16:19
	System	30 Mar 2021 16:16:19

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-05T20:13:02-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '82e3fbc4-0cd9-4a59-a708-0d5e92abdbff' User entered 'No (N)'	System	06 Apr 2021 00:13:10

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-05T20:13:04-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '82e3fbc4-0cd9-4a59-a708-0d5e92abdbff' User entered 'No (N)'	System	06 Apr 2021 00:13:10

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-05T20:13:08-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '82e3fbc4-0cd9-4a59-a708-0d5e92abdbff'	System	06 Apr 2021 00:13:10
User entered '05 Apr 2021 20:13:08'	System	06 Apr 2021 00:13:10

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-14T12:01:06-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3687ec03-801d-41d4-b1c4-10b69c901a0a' User entered 'No (N)'	System	14 Apr 2021 16:02:44
	System	14 Apr 2021 16:02:44

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-14T12:01:11-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3687ec03-801d-41d4-b1c4-10b69c901a0a' User entered 'No (N)'	System	14 Apr 2021 16:02:44
	System	14 Apr 2021 16:02:44



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-14T12:01:14-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3687ec03-801d-41d4-b1c4-10b69c901a0a' User entered '14 Apr 2021 12:01:14'	System	14 Apr 2021 16:02:44
	System	14 Apr 2021 16:02:44

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-23T09:59:04-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9428f2fe-07e1-4215-9919-2e85fbf9034e' User entered 'No (N)'	System	23 Apr 2021 13:59:14
	System	23 Apr 2021 13:59:14

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-23T09:59:08-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9428f2fe-07e1-4215-9919-2e85fbf9034e' User entered 'No (N)'	System	23 Apr 2021 13:59:14
	System	23 Apr 2021 13:59:14

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-23T09:59:11-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9428f2fe-07e1-4215-9919-2e85fbf9034e' User entered '23 Apr 2021 09:59:11'	System	23 Apr 2021 13:59:14
	System	23 Apr 2021 13:59:14

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-30T08:37:20-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ad45cd2c-01ca-479c-9db6-ef7d0de95228'	System	30 Apr 2021 12:37:28
User entered 'No (N)'	System	30 Apr 2021 12:37:28

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-30T08:37:24-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ad45cd2c-01ca-479c-9db6-ef7d0de95228'	System	30 Apr 2021 12:37:28
User entered 'No (N)'	System	30 Apr 2021 12:37:28

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-04-30T08:37:26-04:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ad45cd2c-01ca-479c-9db6-ef7d0de95228'	System	30 Apr 2021 12:37:28
User entered '30 Apr 2021 08:37:26'	System	30 Apr 2021 12:37:28

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 19:53:36



**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

**US3692016**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:24:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:59

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 14:10:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-02T05:52:11-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c36c89-4439-4489-92a9-6ddcf59139d3'	System	02 Mar 2021 10:52:17
User entered 'No (N)'	System	02 Mar 2021 10:52:17

**US3692016**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:10:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2021-03-02T05:52:14-05:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c36c89-4439-4489-92a9-6ddcf59139d3'	System	02 Mar 2021 10:52:17
User entered '02 Mar 2021 05:52:14'	System	02 Mar 2021 10:52:17

**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:55:22

**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:55:22



**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:55:22

**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:55:22

**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:55:32

**US3692016**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 06:13:07
User entered 'I'	System	17 Nov 2020 14:55:32

**US3692016**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Joy Wannamaker (b) (4)	23 Dec 2020 15:09:55

**US3692016**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '23 Dec 2020'	Joy Wannamaker (b) (4)	23 Dec 2020 15:09:55

**US3692016**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Contact Made (CONTACT MADE)'	Joy Wannamaker (b) (4)	23 Dec 2020 15:09:55

US3692016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'No changes to health or medications at this time. New consent reviewed and signed.'	Joy Wannamaker (b) (4)	23 Dec 2020 15:09:55



**US3692016**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Joy Wannamaker (b) (4)	23 Dec 2020 15:10:01

**US3692016**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:10
User entered 'I'	System	23 Dec 2020 15:10:01

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:39:06

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '18 Jan 2021'	Camille O'Reilly (b) (4)	18 Jan 2021 18:39:06

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:39:06

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	Camille O'Reilly (b) (4)	18 Jan 2021 18:39:06

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:39:16

**US3692016**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'I'	System	18 Jan 2021 18:39:16



**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Feb 2021 21:53:15

**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '18 Feb 2021'	Camille O'Reilly (b) (4)	18 Feb 2021 21:53:15

**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4)	18 Feb 2021 21:53:15

**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	Camille O'Reilly (b) (4)	18 Feb 2021 21:53:15

**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Feb 2021 21:53:24

**US3692016**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'I'	System	18 Feb 2021 21:53:24

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:02

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:02



**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:02

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'VISIT4'	System	17 Mar 2021 14:11:02

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

US3692016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '09:08'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered '17 Mar 2021 09:08'	System	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17



**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '70'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'bpm'	System	30 Mar 2021 21:28:17

US3692016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

US3692016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'breaths/min'	System	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '123'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'mmHg'	System	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:16:13
User entered '81'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:28:17



**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'mmHg'	System	30 Mar 2021 21:28:17

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:12

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:12

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:38

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:38

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '09:11'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:38



**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered '17 Mar 2021 09:11'	System	17 Mar 2021 14:11:38

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:11:50

**US3692016**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:21:19
User entered 'I'	System	17 Mar 2021 14:11:50

**US3692016**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	22 Apr 2021 18:26:37
	(b) (4)	
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	22 Apr 2021 16:47:10
	(b) (4)	

**US3692016**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	22 Apr 2021 18:26:37
	(b) (4)	
User entered '22 Apr 2021'	Camille O'Reilly (b) (4)	22 Apr 2021 16:47:10
	(b) (4)	

**US3692016**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	22 Apr 2021 18:26:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Camille O'Reilly (b) (4) (b) (4)	22 Apr 2021 16:47:10

US3692016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:37
User entered empty.	Camille O'Reilly (b) (4) (b) (4)	22 Apr 2021 16:47:10

**US3692016**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:37
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	22 Apr 2021 16:47:22



**US3692016**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 16:47:22

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:08

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '9 Jan 2021'	Erin Cardot (b) (4)	09 Jan 2021 15:10:08

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:59

[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 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Clinic (Clinic)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:08

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 15:10:08

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '9 Jan 2021'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	12 Mar 2021 19:17:44
User entered '0'	(b) (4) Erin Cardot (b) (4)	08 Mar 2021 18:44:35
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:53:20

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23



**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	12 Mar 2021 19:17:44
User entered 'Amendment 6 or later (Amendment 6 or later)'	Erin Cardot (b) (4)	08 Mar 2021 18:44:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:53:20

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '9 Jan 2021'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:16:08
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23
	(b) (4)	

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:16:08
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23
	(b) (4)	

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:23

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '1'	System	09 Jan 2021 15:10:23

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'I'	System	09 Jan 2021 15:10:23



US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '185' cm	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '110.9' kg	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:24:59**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '32.40321'	System	12 Jan 2021 15:25:04
DataPoint set to visible.	System	09 Jan 2021 15:10:23

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '185' cm	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '110.9' kg	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:24:59**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '32.40321'	System	12 Jan 2021 15:25:04
DataPoint set to visible.	System	09 Jan 2021 15:10:23

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User accepted default value 'Pre-Dose (PREDOSE)'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04



US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:18:02
Comment added 'We received permission from monitor/Sponsor to conduct Decision Visits and OL-1 Visits on separate days. Date of vital sign collection reflects date of OL-1 visit.'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:26:05
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Jan 2021 15:25:04
User entered '11 Jan 2021'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '10:01'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '11 Jan 2021 10:01'	System	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 03:38:01
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:26:10
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Jan 2021 15:25:04
User entered '35.0' C	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Oral (Oral)'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered empty.	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '71'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'bpm'	System	12 Jan 2021 15:25:04



US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '18'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'breaths/min'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '125'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '76'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '185' cm	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '110.9' kg	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04



**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:24:59**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '32.40321'	System	12 Jan 2021 15:25:04
DataPoint set to visible.	System	09 Jan 2021 15:10:23

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User accepted default value 'Post-Dose (POSTDOSE)'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:18:07
Comment added 'We received permission from monitor/Sponsor to conduct Decision Visits and OL-1 Visits on separate days. Date of vitals is date of OL-1 visit/dosing.'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:26:57
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Jan 2021 15:25:04
User entered '11 Jan 2021'	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '12:03'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered '11 Jan 2021 12:03'	System	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 03:38:40
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:27:01
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Jan 2021 15:25:04
User entered '35.2' C	Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Oral (Oral)'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04



**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered empty.	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '70'	Maria Stetson (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'bpm'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '16'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'breaths/min'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '119'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '78'	(b) (4) Maria Stetson (b) (4) (b) (4)	12 Jan 2021 15:25:04



**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:15
User entered 'mmHg'	System	12 Jan 2021 15:25:04

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Maria Stetson (b) (4)	12 Jan 2021 15:32:06

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09 Jan 2021'	Maria Stetson (b) (4)	12 Jan 2021 15:32:06

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	11 Jan 2021 16:47:37

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	Mandy Tipton (b) (4)	11 Jan 2021 16:47:37

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	Mandy Tipton (b) (4)	11 Jan 2021 16:47:37

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mRNA-1273'	System	11 Jan 2021 16:47:37
DataPoint set to visible.	System	09 Jan 2021 15:10:23

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 10:20:58
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Date is correct. Day 0 and OL-1 visits completed in separate visits.' (Site from System).	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 16:48:42
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	11 Jan 2021 16:47:37
User entered '11 Jan 2021'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 16:47:37



US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '11:31'	Mandy Tipton (b) (4)	11 Jan 2021 16:47:37

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '11 Jan 2021 11:31'	System	11 Jan 2021 16:47:37

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4)	11 Jan 2021 16:47:37

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'ONCE'	System	11 Jan 2021 16:47:37

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 16:47:37

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:33:07

US3692016

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09 Jan 2021'	(b) (4) Maria Stetson (b) (4)	12 Jan 2021 15:33:07
	(b) (4)	

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08:55'	Maria Stetson (b) (4)	12 Jan 2021 15:33:07



**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '09 Jan 2021 08:55'	System	12 Jan 2021 15:33:07

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Maria Stetson (b) (4)	12 Jan 2021 15:33:21

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:24:59**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09 Jan 2021'	Maria Stetson (b) (4)	12 Jan 2021 15:33:21

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:24:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09:00'	Maria Stetson (b) (4)	12 Jan 2021 15:33:21

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:24:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '09 Jan 2021 09:00'	System	12 Jan 2021 15:33:21

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Erin Cardot (b) (4)	09 Jan 2021 15:10:34

**US3692016**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'I'	System	09 Jan 2021 15:10:34

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:38:02



**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '18 Jan 2021'	Camille O'Reilly (b) (4)	18 Jan 2021 18:38:02

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:38:02

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	Camille O'Reilly (b) (4)	18 Jan 2021 18:38:02

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Camille O'Reilly (b) (4)	18 Jan 2021 18:38:28

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User entered 'I'	System	18 Jan 2021 18:38:28

**US3692016**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:40
User entered '1'	System	18 Jan 2021 18:38:28
DataPoint set to visible.	System	18 Jan 2021 18:38:28

**US3692016**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:16:29
	(b) (4)	

**US3692016**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08 Feb 2021'	Maria Stetson (b) (4)	08 Feb 2021 14:16:29



**US3692016**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[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 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Clinic (Clinic)'	Maria Stetson (b) (4)	08 Feb 2021 14:16:29

**US3692016**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'OLD29'	System	08 Feb 2021 14:16:29

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User accepted default value 'Pre-Dose (PREDOSE)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08 Feb 2021'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08:28'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '08 Feb 2021 08:28'	System	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '36.1' C	Maria Stetson (b) (4)	08 Feb 2021 14:38:38



**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Oral (Oral)'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '79'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'bpm'	System	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '16'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'breaths/min'	System	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '132'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mmHg'	System	08 Feb 2021 14:38:38



**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '83'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mmHg'	System	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User accepted default value 'Post-Dose (POSTDOSE)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08 Feb 2021'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09:34'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '08 Feb 2021 09:34'	System	08 Feb 2021 14:38:38

US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '36.6' C	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:38:38



US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Oral (Oral)'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '63'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'bpm'	System	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '16'	Maria Stetson (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'breaths/min'	System	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '142'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mmHg'	System	08 Feb 2021 14:38:38



US3692016

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '87'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mmHg'	System	08 Feb 2021 14:38:38

**US3692016**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:18:10

**US3692016**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08 Feb 2021'	Maria Stetson (b) (4)	08 Feb 2021 14:18:10

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:16:58

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:16:58

US3692016

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered empty.	(b) (4) Maria Stetson (b) (4)	08 Feb 2021 14:16:58
	(b) (4)	

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'mRNA-1273'	System	08 Feb 2021 14:16:58
DataPoint set to visible.	System	18 Jan 2021 18:38:28



US3692016

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '08 Feb 2021'	Maria Stetson (b) (4)	08 Feb 2021 14:16:58

US3692016

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '09:03'	(b) (4) Maria Stetson (b) (4) (b) (4)	08 Feb 2021 14:16:58

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered '08 Feb 2021 09:03'	System	08 Feb 2021 14:16:58

US3692016

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Left Arm (LEFT ARM)'	Maria Stetson (b) (4)	08 Feb 2021 14:16:58

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'ONCE'	System	08 Feb 2021 14:16:58

**US3692016**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:24:59**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 14:16:58

**US3692016**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Maria Stetson (b) (4)	08 Feb 2021 14:17:16

**US3692016**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:51
User entered 'I'	System	08 Feb 2021 14:17:16



**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Yes (Y)'	Oesa Vinesett (b) (4)	24 Feb 2021 18:48:38

**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered '15 Feb 2021'	Oesa Vinesett (b) (4)	24 Feb 2021 18:48:38

**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Contact Made (CONTACT MADE)'	Oesa Vinesett (b) (4)	24 Feb 2021 18:48:38

**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:24:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered empty.	Oesa Vinesett (b) (4)	24 Feb 2021 18:48:38

**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User signature succeeded.	Cynthia Gay (b) (4)	05 Mar 2021 20:57:51
User entered 'Yes (Y)'	Oesa Vinesett (b) (4)	24 Feb 2021 18:48:45

**US3692016**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:24:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:12
User entered 'I'	System	24 Feb 2021 18:48:45

**US3692016**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:08:17

**US3692016**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:08:17



**US3692016**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[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 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:08:17

**US3692016**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:24:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered 'OLD57'	System	17 Mar 2021 14:08:17

US3692016

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 20:15:23
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'Entered VS in Day 209' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 21:40:51
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 01:30:01
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '09:08'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered '17 Mar 2021 09:08'	System	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20



**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered 'bpm'	System	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered 'breaths/min'	System	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '123'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered 'mmHg'	System	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '81'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:20



**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered 'mmHg'	System	17 Mar 2021 14:09:20

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55

**US3692016**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:24:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55

**US3692016**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:38

**US3692016**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:24:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:09:38

**US3692016**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:10:03

**US3692016**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:10:03

**US3692016**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:52
User entered '09:11'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:10:03



**US3692016**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:24:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:55
User entered '17 Mar 2021 09:11'	System	17 Mar 2021 14:10:03

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:24:59**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:50
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'Yes (Y)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:14:58

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4)	
(Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:06:05
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	Erin Cardot (b) (4)	19 Nov 2020 14:29:57
' answered with 'Participant was assessed for COVID-19, per protocol.' (Site from DM).	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4), (b) (6)	19 Nov 2020 13:04:34
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 23:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 23:18:31
User entered 'tachypnea'	Kristi Kirkland (b) (4)	23 Oct 2020 23:18:27
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '23 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27



US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
User closed query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:14:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:13:47
Query 'Data is required. Please provide.' answered with 'Updated.' (Site from System).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 21:53:52
DataPoint Un-verified.	System	10 Nov 2020 21:53:52
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
Query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' answered with 'VS measurement taken at Day 29 visit, within 24 hours of IP.' (Site from DM).	Maria Stetson (b) (4)	10 Nov 2020 14:27:29
User opened query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:21:19
User closed query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:16:49

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' answered with 'Data point is within 24hrs of the 2nd vaccination.' (Site from DM).	Mandy Tipton (b) (4)	03 Nov 2020 01:22:26
User entered '08:18' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 01:22:20
User opened query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 03:26:04
User entered '8:18'	Kristi Kirkland (b) (4)	23 Oct 2020 23:18:27
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User entered empty.	System	10 Nov 2020 21:53:52
User entered '23 Sep 2020 08:18'	System	03 Nov 2020 01:22:20
User entered '23 Sep 2020 8:18'	System	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 05:32:29
User closed query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:32:26
Query 'Data is required. Please provide.' answered with 'Time is not required. ' (Site from System).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:26
Query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' answered with 'Updated. ' (Site from DM).	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:15
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	System	10 Nov 2020 21:53:52
DataPoint Verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
	(b) (4)	
	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
	(b) (4), (b) (6)	04 Nov 2020 06:28:05
User opened query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' (Site from DM).		
User closed query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:22:26
User entered '08:03' reason for change: Data Entry Error	Mandy Tipton (b) (4)	03 Nov 2020 01:22:44
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Query ' Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you.  ' answered with 'Data point is within 24hrs of the 2nd vaccination.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:22:37
User opened query ' Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	02 Nov 2020 03:27:05
User entered '8:03'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User entered empty.	System	10 Nov 2020 21:53:52
User entered '23 Oct 2020 08:03'	System	03 Nov 2020 01:22:44
User entered '23 Oct 2020 8:03'	System	23 Oct 2020 23:18:27



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'I'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User entered '0'	System	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30
User entered '0'	System	23 Oct 2020 23:18:27

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:59:30



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:36:15
User entered	System	03 Nov 2020 20:35:35
'USA-US123-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 20:35:35

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of ILIAC ARTERY ANEURYSM noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 07:49:57
Query 'Per DM CLR: Please confirm if this AE is a worsening of ILIAC ARTERY ANEURYSM noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'Documented as an SAE due inpatient hospitalization. This was an elective repair of the iliac artery aneurysm.' (Site from DM).	Oesa Vinesett (b) (4) (b) (4)	01 Dec 2020 15:32:52
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ILIAC ARTERY ANEURYSM noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 15:18:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Peripheral aneurysms and dissections, PT: Peripheral artery aneurysm, LLT: Iliac artery aneurysm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 01:43:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 01:43:11
Data point term sent to Coder	System	03 Nov 2020 01:42:24
User entered 'iliac artery aneurysm'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '01 Nov 2020'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 01:41:56



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 23:27:09
DataPoint Un-verified.		
	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
User entered '02 Nov 2020' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:27:11
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 21:52:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 21:52:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 21:52:30
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
User entered '08 Nov 2020' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 23:27:13
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:38:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	



US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 05:33:35
Query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' answered with 'Resolved.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	10 Nov 2020 21:53:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User opened query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:42:52
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)	04 Nov 2020 06:37:55
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 'Discharge date pending.' (Site from System).	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:42:45
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	03 Nov 2020 01:41:56
User entered 'I'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '01 Nov 2020'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 23:28:43
DataPoint Un-verified.		
	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
User entered '08 Nov 2020' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.		
	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 23:28:30
DataPoint Un-verified.		
	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
User entered '4' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '1'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
User entered '1' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	



**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Applicable (NOT APPLICABLE)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
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) (4), (b) (6)	15 Dec 2020 04:02:35
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 'Indications for concomitant medications clarified to show relationship to procedure.' (Site from DM).	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:16:24
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)	12 Dec 2020 04:00:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'I'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'I'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 23:28:43
DataPoint Un-verified.		
	Mandy Tipton (b) (4)	10 Nov 2020 21:52:57
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mandy Tipton (b) (4)	10 Nov 2020 21:52:57
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	



US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'PV Query: Per medical history, the Iliac artery aneurysm was found in 2017. Please confirm if there was worsening of the Iliac artery aneurysm. If yes, please update event term to include this.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:19:36
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)	07 Dec 2020 14:19:34
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 'On 30-Oct-2020, participant was tested for COVID-19 via PCR nasal swab as part of pre-procedure screening. This NP swab resulted negative for COVID-19.' (Site from Safety).	Maria Stetson (b) (4) (b) (4)	04 Dec 2020 14:34:29
Query 'PV Query: Per medical history, the Iliac artery aneurysm was found in 2017. Please confirm if there was worsening of the Iliac artery aneurysm. If yes, please update event term to include this.' answered with 'There was not a worsening of iliac artery aneurysm that led to this procedure. The procedure to repair the aneurysm was elective and not triggered by a worsening of the condition.' (Site from Safety).	Maria Stetson (b) (4) (b) (4)	04 Dec 2020 14:28:09
User opened query 'PV Query: Per medical history, the Iliac artery aneurysm was found in 2017. Please confirm if there was worsening of the Iliac artery aneurysm. If yes, please update event term to include this.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:49:47
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)	25 Nov 2020 11:49:35
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 13:55:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 13:55:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A.' (Site from Safety).	Maria Stetson (b) (4)	16 Nov 2020 14:49:28
Query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' answered with 'Consistent with SAE reporting criteria as outlined on page 74 of Protocol Amendment 4, due to inpatient hospitalization, requiring overnight stay.' (Site from Safety).	Maria Stetson (b) (4)	16 Nov 2020 13:14:21
User entered 'ADMITTED FOR ELECTIVE OPEN REPAIR OF 3.7CM RIGHT ILIAC ANEURYSM, WHICH WAS AN INCIDENTAL FINDING IN 2017. REPAIR WENT WELL AND STAYED IN HOSPITAL POST-SURGERY FOR PAIN MANAGEMENT. DISCHARGED WITHOUT COMPLICATIONS ON 08-NOVEMBER-2020. Consistent with SAE reporting criteria as outlined on page 74 of Protocol Amendment 4, due to inpatient hospitalization.' reason for change: New Information DataPoint Un-verified.	Maria Stetson (b) (4)	16 Nov 2020 13:14:02
	(b) (4)	
User entered 'ADMITTED FOR ELECTIVE OPEN REPAIR OF 3.7CM RIGHT ILIAC ANEURYSM, WHICH WAS AN INCIDENTAL FINDING IN 2017. REPAIR WENT WELL AND Stayed in hospital post-surgery FOR PAIN MANAGEMENT. Discharged without complications on 08-November-2020.' reason for change: New Information	Maria Stetson (b) (4)	16 Nov 2020 13:13:26
	(b) (4)	
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:08:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1921 of 2433

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:08:29
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Admitted for elective open repair of 3.7cm right iliac aneurysm, which was an incidental finding in 2017. Repair went well and remains admitted for pain management. Updates to follow.'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 01:41:56

**US3692016**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 01:41:56

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:50
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:32:34
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:13:57

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:18:44
Data point term sent to Coder	System	01 Sep 2020 18:18:14
User entered 'singulair'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'reactive-airway disease'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '10'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:21:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 18:21:10
User entered 'No (N)' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:21:10
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:17:26
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:17:26

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:17:26

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:17:26



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:23:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:23:57
Data point term sent to Coder User entered 'zetia'	System Abigail Riddick (b) (4)	01 Sep 2020 18:23:27 01 Sep 2020 18:23:17

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'secondary prevention for cardiovascular disease'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '10'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:23:17



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:23:17

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:23:17

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:18:52
Data point term sent to Coder	System	01 Sep 2020 18:27:39
User entered 'rosuvastatin'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:39:40
Query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' answered with 'documented' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:12:24
User opened query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:14:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:14:09
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'confirmed' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	10 Oct 2020 17:06:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 02:52:11
User entered 'slow progression of atherosclerosis'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'every other day (QOD)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un Jun 2019'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	18 Oct 2020 13:57:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '12 Oct 2020' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	18 Oct 2020 13:57:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User entered '1'	System	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User entered '2'	System	01 Sep 2020 18:27:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:11:40
User entered '804 (804)'	System	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE, PRODUCTSYNONYM: PULMICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:34:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:34:50
Data point term sent to Coder	System	01 Sep 2020 18:31:52
User entered '(budesonide) pulmicort inhaler'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'reactive airway disease'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '2'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'puff (PUFF)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2000'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:31:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:37
Data point term sent to Coder	System	01 Sep 2020 18:33:58
User entered 'glucosamine - chondroitin capsule'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:33:37



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'joint health'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1500/200'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:33:37

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:37

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:37



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ALLIUM SATIVUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:36
Data point term sent to Coder	System	01 Sep 2020 18:36:08
User entered 'garlic'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'unknown'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'capsule (CAPSULE)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:20

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:20

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:02:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:02:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:31:43
Data point term sent to Coder	System	01 Sep 2020 18:41:21
User entered 'tumeric capsule'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:41:11

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'joint health'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1350'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:41:11

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:41:11

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:41:11

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 18:42:26
User entered 'aspirin'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '81'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:42:24

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:42:24

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:42:24

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:42:24

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
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)	06 Sep 2020 09:17:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 09:17:57
Data point term sent to Coder	System	01 Sep 2020 18:44:32
User entered 'multivitamin for men'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:43:37



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'health promotion'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'I'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'tablet (TABLET)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:43:37

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:43:37

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:43:37



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:25:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:25:36
Data point term sent to Coder	System	01 Sep 2020 18:57:06
User entered 'fish oil capsules'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:56:12

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'health promotion'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1400'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:56:12

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:56:12

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:56:12

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ZINGIBER OFFICINALE, PRODUCTSYNONYM: GINGER [ZINGIBER OFFICINALE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:54:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:54:02
Data point term sent to Coder	System	01 Sep 2020 18:58:12
User entered 'ginger'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'I'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'capsule (CAPSULE)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:57:21

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:57:21

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:57:21

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;COLECALCIFEROL, PRODUCTSYNONYM: CITRACAL [CALCIUM CITRATE;COLECALCIFEROL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:01:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:01:41
Data point term sent to Coder	System	08 Sep 2020 19:44:54
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	08 Sep 2020 19:44:48
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Updated. ' (Site from System).	Mandy Tipton (b) (4) (b) (4)	08 Sep 2020 19:44:48
User entered 'CITRACAL (calcium and vitamin D3)' reason for change: Per Query Resolution	Mandy Tipton (b) (4) (b) (4)	08 Sep 2020 19:44:40
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	07 Sep 2020 12:17:47
Data point term sent to Coder	System	01 Sep 2020 18:59:15
User entered 'citracal'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'bone health'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:41:38
Query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' answered with 'confirmed' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:12:51
User opened query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:15:29
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:15:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' answered with 'unk dose ' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:56:38
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 02:50:45
User entered '1'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'tablet (TABLET)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:58:36

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:58:36

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:12:38
Data point term sent to Coder	System	01 Sep 2020 19:00:16
User entered 'coenzyme q10'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:59:48



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '400'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'every other day (QOD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:59:48

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:59:48



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 13:59:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 13:59:19
Data point term sent to Coder User entered 'lisinopril'	System Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:11 18 Oct 2020 13:59:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'hypertension'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '21 Sep 2020'	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Kristi Kirkland (b) (4)	18 Oct 2020 13:59:08
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 13:59:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 13:59:08

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
Data point term sent to Coder	System	18 Oct 2020 14:00:11
User entered 'rosuvastatin'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'hperlipidemia'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'other (OTHER)'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '2x a week'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '12 Oct 2020'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Kristi Kirkland (b) (4)	18 Oct 2020 14:00:09
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:16:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:16:37
Data point term sent to Coder	System	13 Nov 2020 21:16:06
User entered 'Tylenol'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Pain (post-bilateral iliac aneurysm repair)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '325'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '2 tablets Q6N'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#3 ILIAC ARTERY ANEURYSM (02NOV2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#3 ILIAC ARTERY ANEURYSM (02NOV2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'AE #3 refers to the procedure that took place, in addition to the time spent in the hospital. The conmed is taken for post-procedure pain.' (Site from DM).	Oesa Vinesett (b) (4)	07 Dec 2020 15:16:50
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#3 ILIAC ARTERY ANEURYSM (02NOV2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:31:41
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15
	(b) (4)	



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:43:04
User entered 'No (N)' reason for change: New Information	(b) (4)	08 Feb 2021 14:43:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '31 Dec 2020' reason for change: Data Entry Error	System	08 Feb 2021 14:43:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	Maria Stetson (b) (4)	08 Feb 2021 14:43:19
DataPoint Un-verified.	(b) (4)	
User entered '31 Dec 2021' reason for change: New Information	System	08 Feb 2021 14:43:04
DataPoint Verified.	Maria Stetson (b) (4)	08 Feb 2021 14:43:04
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
	(b) (4)	
	Maria Stetson (b) (4)	13 Nov 2020 21:15:15
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User entered empty.	System	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User entered empty.	System	13 Nov 2020 21:15:15

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:06
User entered empty.	System	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:02:47
Data point term sent to Coder	System	14 Dec 2020 16:13:30
Coding entries removed.	Maria Stetson (b) (4)	14 Dec 2020 16:13:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:16:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:16:37
Data point term sent to Coder	System	13 Nov 2020 21:16:06
User entered 'Colace'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:52:35
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication. Update Con Med eCRF as appropriate.' answered with 'Indication clarified' (Site from DM).	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:13:36
DataPoint Un-verified.	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:13:26
User entered 'STOOL SOFTENER FOLLOWING ILIAC ARTERY ANEURYSM PROCEDURE' reason for change: Per Query Resolution	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:13:26
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:32:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Stool softner'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '100'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:44:41
User entered 'No (N)' reason for change: New Information	(b) (4)	08 Feb 2021 14:44:41
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:44:41
User entered '08 Nov 2020' reason for change: New Information	(b) (4)	08 Feb 2021 14:44:41
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:16:04
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User entered '1'	System	13 Nov 2020 21:16:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User entered '1'	System	13 Nov 2020 21:16:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:10
User entered '804 (804)'	System	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:38:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:38:35
Data point term sent to Coder	System	13 Nov 2020 21:21:12
User entered 'Dilaudid'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Pain (post bilateral iliac aneurysm repair)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '2'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1 tablet prn/Q4 hours for up to 5 days'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '13 Nov 2020'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:20:42



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User entered empty.	System	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User entered empty.	System	13 Nov 2020 21:20:42

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:24
User entered empty.	System	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:15:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:15:57
Data point term sent to Coder	System	14 Dec 2020 16:14:33
Coding entries removed.	Maria Stetson (b) (4)	14 Dec 2020 16:14:27
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:23:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:23:34
Data point term sent to Coder	System	13 Nov 2020 21:23:14
User entered 'Senokot'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication instead of drug action. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:11
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication instead of drug action. Update Con Med eCRF as appropriate.' answered with 'Indication clarified' (Site from DM).	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:14:40
DataPoint Un-verified.	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:14:27
User entered 'STIMULANT LAXATIVE - Following Iliac Artery Aneurysm Procedure' reason for change: Per Query Resolution	Maria Stetson (b) (4) (b) (4)	14 Dec 2020 16:14:27
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic/treatment indication instead of drug action. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:32:54
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Stimulant Laxative'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '17.2'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'twice daily (BID)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:41:48
User entered 'No (N)' reason for change: New Information	(b) (4)	08 Feb 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	08 Feb 2021 14:41:48
User entered '08 Nov 2020' reason for change: New Information	(b) (4)	08 Feb 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:22:23
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User entered '2'	System	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User entered '1'	System	13 Nov 2020 21:22:23

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:12:28
User entered '804 (804)'	System	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:27:35
Data point term sent to Coder	System	13 Nov 2020 21:26:17
User entered 'Cialis'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Erectile dysfunction'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '10'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1-2 tablets prn'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	04 Dec 2020 14:43:15
User entered 'UN UNK 2010' reason for change: New Information	Maria Stetson (b) (4)	04 Dec 2020 14:43:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:25:58



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	(b) (4)	
	Maria Stetson (b) (4)	04 Dec 2020 14:43:15
User entered '0' reason for change: New Information	(b) (4)	
	Maria Stetson (b) (4)	04 Dec 2020 14:43:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: CRIES PROPHYLACTIC AGENTS, PRODUCT: SODIUM FLUORIDE, PRODUCTSYNONYM: PREVIDENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:41
Data point term sent to Coder	System	13 Nov 2020 21:36:27
User entered 'Prevident 1.1%'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral hygiene'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'I'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'administration'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral toothpaste'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	04 Dec 2020 14:41:53
User entered 'UN UNK 2005' reason for change: New Information	Maria Stetson (b) (4)	04 Dec 2020 14:41:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	04 Dec 2020 14:41:53
User entered '0' reason for change: New Information	Maria Stetson (b) (4)	04 Dec 2020 14:41:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4)	13 Nov 2020 21:36:04
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:36:04

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:36:04



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL, PRODUCTSYNONYM: PREVENTIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:17:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:17:41
Data point term sent to Coder	System	14 Dec 2020 16:15:36
Coding entries removed.	Maria Stetson (b) (4)	14 Dec 2020 16:15:34
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User closed query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 21:46:04
Query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' answered with 'Updated.' (Site from CRA).	Mandy Tipton (b) (4)	16 Nov 2020 19:14:40
User opened query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:57:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL, PRODUCTSYNONYM: PREVENTIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:53:36
Data point term sent to Coder	System	13 Nov 2020 21:37:29
User entered 'Preventil'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Indication clarified' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:54:37
DataPoint Un-verified.	Maria Stetson (b) (4)	14 Dec 2020 16:15:41
User entered 'Reactive Airway Disease/Environmental Allergies' reason for change: Per Query Resolution	(b) (4) Maria Stetson (b) (4)	14 Dec 2020 16:15:34
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:33:55
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Wheezing'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '180'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'ug (ug)'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'PRN Q6 hours'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:37:16
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	04 Dec 2020 14:42:26
User entered 'UN UNK 2006' reason for change: New Information	Maria Stetson (b) (4)	04 Dec 2020 14:42:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	04 Dec 2020 14:42:26
User entered '0' reason for change: New Information	Maria Stetson (b) (4)	04 Dec 2020 14:42:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4)	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

Name of Medication

Audit	User	Time (GMT)
User closed query 'Source Hospital discharge notes (Dated 14Dec20200 indicate 3 new Con Meds not listed. Please verify and add.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Cynthia Gay (b) (4)	24 Mar 2021 16:58:36 19 Feb 2021 23:36:05
Query 'Source Hospital discharge notes (Dated 14Dec20200 indicate 3 new Con Meds not listed. Please verify and add.' answered with 'Will confirm/update at next appointment.' (Site from CRA).	Mandy Tipton (b) (4) (b) (4)	27 Jan 2021 21:08:50
User opened query 'Source Hospital discharge notes (Dated 14Dec20200 indicate 3 new Con Meds not listed. Please verify and add.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 21:06:01
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:02:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:02:58
Data point term sent to Coder Coding entries removed.	System Maria Stetson (b) (4)	17 Nov 2020 16:47:49 17 Nov 2020 16:47:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:17:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:17:57
Data point term sent to Coder User entered 'clindamycin 1%'	System Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:17:06 16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:47
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
User entered 'Folliculitis' reason for change: Data Entry Error	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'acne'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'I'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34



**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'application'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Topical (TOPICAL)'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
User entered 'UN UNK 2005' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
User entered '0' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34



US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:24:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 19:16:34

**US3692016**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:24:59**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:50
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:47:18
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:02:15

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered '02 Nov 2020'	Mandy Tipton (b) (4)	12 Nov 2020 19:16:39
	(b) (4)	

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered 'open iliac artery repair'	Mandy Tipton (b) (4)	12 Nov 2020 19:16:39
	(b) (4)	



**US3692016**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered 'Medical History (MH)'	Mandy Tipton (b) (4)	12 Nov 2020 19:16:39
	(b) (4)	

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered empty.	Mandy Tipton (b) (4)	12 Nov 2020 19:16:39
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered		
'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:24:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered '03/Nov/2020 20:37'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35



US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:24:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered '11/Nov/2020 19:30'	System	12 Nov 2020 00:30:19

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 00:30:19

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:24:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '17/Nov/2020 13:56'	(b) (4) System	17 Nov 2020 13:56:04

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:24:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 23:05:35
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 13:56:04



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:24:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
	(b) (4)	
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23



**US3692016**

**Folder: SAE USA-US123-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:24:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered '18/Nov/2020 18:05'	(b) (4) System	18 Nov 2020 23:05:52

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:24:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:36:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:05:52