

US3162007 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:26:31

All time stamps listed in this document are displayed in GMT

US3162007

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

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Participant ID

US3162007

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

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US3162007

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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

Visit date (dd MMM yyyy)	27 JUL 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3162007

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Date of Informed Consent (*dd MMM yyyy*) 27 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3162007

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:14:26

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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) 12 Feb 2021 21:14:26

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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) 12 Feb 2021 21:14:26

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Condition	OSTEOPOROSIS
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)	_____

US3162007

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 21:14:26

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Condition	OSTEOARTHRITIS (BILATERAL HANDS, BILATERAL KNEES, NECK)
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) 12 Feb 2021 21:14:26

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Condition	VITAMIN B12 DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3162007

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	27 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	18:11 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 18:11
Height ( <i>xxx.x</i> )	64.5 in
Weight ( <i>xxx.x</i> )	113.2 lb
BMI ( <i>xxx.x</i> )	19.17065 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) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:14:26

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Date of assessment (dd MMM yyyy) 27 JUL 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1999

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:14:26

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:14:26

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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) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 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

US3162007

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

What was the date of randomization? (dd MMM yyyy) 27 JUL 2020

What was the participant's randomization number? 184067

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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)	27 JUL 2020
Time of assessment (00:00-23:59)	18:11 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 18:11
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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)	27 JUL 2020
Time of assessment (00:00-23:59)	19:10 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 19:10
Temperature (xxx.x)	97.6 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG



US3162007

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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.*

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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) 27 JUL 2020

What was the treatment time? (00:00-23:59) 18:39 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 18:39

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) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JUL 2020
Collection time (00:00-23:59)	18:33 (24 HR)
Collection date and time (derived)	27 JUL 2020 18:33

US3162007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Collection date (dd MMM yyyy)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:37	27 JUL 2020 18:37
Nasopharyngeal Swab 2	No		

US3162007

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 JUL 2020 20:20

PC Open Date & Time

27 JUL 2020 18:59

PC Close Date & Time

27 JUL 2020 21:29

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**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 97.1 °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	28 JUL 2020 07:31
PC Open Date & Time	27 JUL 2020 22:24
PC Close Date & Time	28 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**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

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 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**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

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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

27 JUL 2020 20:25

PC Open Date & Time

27 JUL 2020 18:59

PC Close Date & Time

27 JUL 2020 21:29

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**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

28 JUL 2020 07:31

PC Open Date & Time

27 JUL 2020 22:24

PC Close Date & Time

28 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**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

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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 ☐

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

No ☒

Yes ☐

PC Time stamp	27 JUL 2020 20:23
PC Open Date & Time	27 JUL 2020 18:59
PC Close Date & Time	27 JUL 2020 21:29

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**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 ☐



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 07:32
PC Open Date & Time	27 JUL 2020 22:24
PC Close Date & Time	28 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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Form: General\_Day(2)

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Yes ☐

PC Time stamp

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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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Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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Yes ☐

PC Time stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**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  
EAB) (1725)

55 of 2350



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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)

57 of 2350

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

59 of 2350

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:18

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3162007

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:18

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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)	31 AUG 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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)	31 AUG 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:39
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3162007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 13:01

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



US3162007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

12:08 (24 HR)

Collection date and time (derived)

31 AUG 2020 12:08

US3162007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	31 AUG 2020 12:15
Nasopharyngeal Swab 2	No		

US3162007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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

97.1 °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 13:41

PC Open Date & Time 31 AUG 2020 13:21

PC Close Date & Time 31 AUG 2020 15:51

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**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 ☒

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 08:45
PC Open Date & Time	31 AUG 2020 16:46
PC Close Date & Time	01 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**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

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

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

---

PC Time Stamp 02 SEP 2020 20:04

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PC Open Date & Time 02 SEP 2020 12:00

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PC Close Date & Time 03 SEP 2020 11:59

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US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

03 SEP 2020 16:56

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**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

98.2 °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

04 SEP 2020 22:04

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 09:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 07:35

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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

31 AUG 2020 13:43

PC Open Date & Time

31 AUG 2020 13:21

PC Close Date & Time

31 AUG 2020 15:51

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

40

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 08:51

PC Open Date & Time

31 AUG 2020 16:46

PC Close Date & Time

01 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

40

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

03 SEP 2020 17:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

04 SEP 2020 22:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**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

06 SEP 2020 09:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**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

07 SEP 2020 07:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**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 ☐

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 15:47
PC Open Date & Time	31 AUG 2020 13:21
PC Close Date & Time	31 AUG 2020 15:51

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**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 ☐

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 AUG 2020 16:46

PC Close Date & Time

01 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**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)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 16:57
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:05
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 10:00
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3162007

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT3

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:33 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:33
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> )	68 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3162007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	25 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:23 (24 HR)
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Collection date and time (derived)	25 SEP 2020 11:23
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US3162007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 SEP 2020 10:25:59
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 OCT 2020 10:20:13

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59



US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 12:31:23

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:06:27

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 08:26:21
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 14:37:26

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 113

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:45:02

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

27 NOV 2020 11:23:26

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 08:31:41

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

12 DEC 2020 22:01:09

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

16 DEC 2020 07:36:39

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 17:39:16

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

30 DEC 2020 08:56:01

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

06 JAN 2021 07:45:45

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

13 JAN 2021 09:00:07

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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 <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	22 JAN 2021 15:47:19
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

27 JAN 2021 08:01:53

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

03 FEB 2021 07:44:52

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

11 FEB 2021 11:45:59

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

17 FEB 2021 08:56:50

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

24 FEB 2021 15:54:33

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 08:22:57
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 10:38:24
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

17 MAR 2021 10:33:00

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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

24 MAR 2021 10:48:50

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 09:01:34

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 08:39:51

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

Date and time of submission

15 APR 2021 09:07:01

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

Date and time of submission

21 APR 2021 07:55:15

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

Date and time of submission

28 APR 2021 08:08:10

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	28 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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 <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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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°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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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°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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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°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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59



US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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°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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

**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 ☐

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3162007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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"/>

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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**US3162007**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 15:26:31**

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		03 MAR 2021 08:24:04

US3162007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:14:26

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:18

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3162007

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:18

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:14:25

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:19

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

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

Visit date (dd MMM yyyy)	19 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3162007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3162007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

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.*

US3162007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	19 FEB 2021
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Collection time (00:00-23:59)	11:15 (24 HR)
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Collection date and time (derived)	19 FEB 2021 11:15
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US3162007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3162007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162007

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3162007**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

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*

**US3162007**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3162007**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:26:31**

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

**US3162007**

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

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

**Generated On: 09 Jun 2021 15:26:31**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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**US3162007**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 09 Jun 2021 15:26:31**

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

**US3162007**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_



US3162007

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3162007

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

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.*

**US3162007**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:26:31**

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
--------------------	--

**US3162007**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3162007

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3162007

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

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.*

**US3162007**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:26:31**

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection \_\_\_\_\_

US3162007

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 12 FEB 2021

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

Folder OID UNBLND\_DECIDE



US3162007

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Date of updated informed consent (dd MMM yyyy) 12 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3162007

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Height	64.5 in
Weight	113.2 lb

US3162007

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Height	64.5 in
Weight	113.2 lb
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)	12 FEB 2021
Time of assessment (00:00-23:59)	17:05 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 17:05
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3162007

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Height	64.5 in
Weight	113.2 lb
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3162007

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

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

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.*

US3162007

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	12 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	17:10 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 FEB 2021 17:10
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US3162007

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00 - 23:59)	17:10
Collection Date and Time (derived)	12 FEB 2021 17:10

US3162007

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

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:25

Generated On: 09 Jun 2021 15:26:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3162007**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

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*

**US3162007**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162007

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

AEID	USA-US074-2020-MRNA-1273-P30 1000001
Adverse event	MILD CEREBROVASCULAR ACCIDENT
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)	30 JUL 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)	31 JUL 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	30 JUL 2020
Hospital Discharge Date (dd MMM yyyy)	31 JUL 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	339 of 2350

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

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

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

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DAY 8 SAFETY CALL DONE.  
SUBJECT REPORTED BEING  
HOSPITALIZED FROM 30JUL TO  
31 JUL 2020 FOR A MILD  
CEREBROVASCULAR  
ACCIDENT. NEW CON MEDS  
NOTED. SAE REPORTED TO  
SPONSOR. SUBJECT WILL  
CONTINUE IN STUDY.  
AS PER SPONSOR QUERY: CPK  
WAS 227U/L ON 30JUL20. VS  
WERE AS FOLLOWS ON  
30JUL20: BP 129/68 HR 61  
CLINICAL COURSE: SUBJECT  
UNDERWENT DUPLEX  
CAROTID SCAN WHICH WAS  
NEGATIVE, BRAIN CT SHOWED  
SMALL ACUTE INFARCT IN  
RIGHT OCCIPITAL LOBE.  
SUBJECT WAS SENT HOME ON  
ASPIRIN AND ATORVASTATIN  
AS NOTED IN CON MEDS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

AEID

Adverse event

OCCIPITAL HEADACHE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 JUL 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 21:07:16

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 21:07:16

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AEID	
Adverse event	URTICARIA TRUNK, INTERMITTENT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 21:07:16

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

AEID	
Adverse event	MEMORY LOSS
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)	29 JUL 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (4)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:07:17

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---

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication MILD CEREBROVASCULAR  
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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)	31 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 21:07:16

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (2)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication ATORVASTATIN

Prophylaxis Yes ☒  
No ☐

Indication MILD CEREBROVASCULAR  
ACCIDENT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 21:07:16

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	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)	1 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	8 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
HANDS, BILATERAL KNEES,  
NECK

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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 2016	
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 (5)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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 2015	
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 (6)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐  
No ☒

Indication URTICARIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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 AUG 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 (7)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication OCCIPITAL HEADACHE

Dose per administration 375

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) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 1 AUG 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"/>

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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)	8 AUG 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"/>

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication URTICARIA

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 (9)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 AUG 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"/>

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication HYDROCORTISONE 2.5%  
CREAM

Prophylaxis Yes ☐  
No ☒

Indication URTICARIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 AUG 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)		3
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) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication VITAMIN B12

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN B12 DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 AUG 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 (12)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication GADAVIST (CONTRAST FOR MRI)

Prophylaxis Yes ☐  
No ☒

Indication CONTRAST FOR MRI PROCEDURE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 JUL 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 JUL 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication OMNIPAQUE 350

Prophylaxis Yes ☐  
No ☒

Indication CONTRAST FOR CT VENOGRAM  
OF HEAD

Dose per administration 97

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 (13)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 JUL 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 JUL 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication PLAVIX

Prophylaxis Yes ☒  
No ☐

Indication STROKE PROPHYLAXIS

Dose per administration 75

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) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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)		17 AUG 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) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication TRIAMCINOLONE 0.1%  
OINTMENT

Prophylaxis Yes ☐  
No ☒

Indication URTICARIA ON ABDOMEN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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)	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)		
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) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication URTICARIA ON ABDOMEN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Feb 2021 21:07:16

Generated On: 09 Jun 2021 15:26:31

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 JUL 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
31 JUL 2020	ULTRASOUND DUPLEX SCAN BILATERAL EXTRACRANIAL CAROTID ARTERIES	Adverse Event	
31 JUL 2020	CT VENOGRAM OF HEAD WITH AND WITHOUT CONTRAST	Adverse Event	
30 JUL 2020	MRI BRAIN AND BRAINSTEM WITH AND WITHOUT CONTRAST	Adverse Event	
24 AUG 2020	CARDIAC EVENT MONITOR (HOLTER)	Adverse Event	
30 JUL 2020	CPK 227	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:26:31

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



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:26:31

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 ☐

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Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/AUG/2020 08:30
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

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/AUG/2020 09:03
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

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/AUG/2020 09:03
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

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/SEP/2020 12:43
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

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/SEP/2020 16:03
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

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/SEP/2020 11:05
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



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Feb 2021 21:07:17

Generated On: 09 Jun 2021 15:26:31

SAEID	USA-US074-2020-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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3162007 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

**US3162007**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:26:31**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	06 Sep 2020 23:11:54
User entered 'US3162007'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:07

US3162007

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:26:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
DataPoint Verified.	com1) (b) (4), (b) (6)	05 Aug 2020 00:19:12
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:36:44
	(b) (4)	

US3162007

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:19:12
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:08

US3162007

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:26:31

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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 00:19:12
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:36:44

**US3162007**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'SCRN'	System	28 Jul 2020 14:36:44

US3162007

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:26:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:09



**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein(b) (4)	12 Feb 2021 21:14:26
User entered '68'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'YEARS'	System	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '68'	System	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Female (F)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

US3162007

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:26:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein(b) (4)	12 Feb 2021 21:14:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13



**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

US3162007

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:26:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

**US3162007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:31**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:13

US3162007

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:26:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jul 2020'	System	28 Jul 2020 01:54:28



**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2020'	System	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

**US3162007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:31**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:28

US3162007

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:26:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:08

US3162007

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:26:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'I'	System	28 Jul 2020 01:54:36



**US3162007**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:36

US3162007

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:26:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:37:30

US3162007

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
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)	28 Jul 2020 14:39:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:39:17
Data point term sent to Coder	System	28 Jul 2020 14:38:07
User entered 'hypertension'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 2013'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:04



**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2013'	System	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2013'	System	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:38:04

**US3162007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:38:04

US3162007

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:26:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:40:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:40:17
Data point term sent to Coder	System	28 Jul 2020 14:39:08
User entered 'osteoporosis'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 2016'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29



**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2016'	System	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2016'	System	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:38:29

**US3162007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:38:29

US3162007

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:48:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:48:10
Data point term sent to Coder	System	28 Jul 2020 14:39:07
User entered 'Uterine firbroids'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 1999'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59



**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 1999'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 1999'	System	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '1999'	System	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 1999'	System	28 Jul 2020 14:38:59

**US3162007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '1999'	System	28 Jul 2020 14:38:59



US3162007

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:55:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:55:13
Data point term sent to Coder	System	28 Jul 2020 14:40:09
User entered 'osteoarthritis (bilateral hands, bilateral knees, neck)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 2016'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2016'	System	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2016'	System	28 Jul 2020 14:39:28



**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:39:28

**US3162007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:39:28

US3162007

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Per DM CLR: Please specify the type of BRADYCARDIA (e.g., sinus or bradycardia). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:45:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus bradycardia, LLT: Sinus bradycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 18:51:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 18:51:49
Data point term sent to Coder	System	14 Sep 2020 18:50:28
Query 'Per DM CLR: Please specify the type of BRADYCARDIA (e.g., sinus or bradycardia). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4)	14 Sep 2020 18:50:21
Coding entries removed.	Judith Kirstein (b) (4)	14 Sep 2020 18:50:09
User entered 'SINUS BRADYCARDIA' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Sep 2020 18:50:09
User opened query 'Per DM CLR: Please specify the type of BRADYCARDIA (e.g., sinus or bradycardia). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:53:08

US3162007

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:26:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 18:00:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 18:00:20
Data point term sent to Coder	System	28 Jul 2020 14:40:08
User entered 'bradycarida'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54
	(b) (4)	

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54



**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2014'	System	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2014'	System	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:39:54

**US3162007**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:39:54

US3162007

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 15:53:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 15:53:12
Data point term sent to Coder	System	28 Jul 2020 14:40:09
User entered 'acid reflux disease'	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09



**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2014'	System	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2014'	System	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:40:09

**US3162007**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	28 Jul 2020 14:40:09

US3162007

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:26:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 04:44:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 04:44:40
Data point term sent to Coder	System	13 Sep 2020 04:43:33
User entered 'Vitamin B12 deficiency'	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12



**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'UN UNK 2014'	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Judith Kirstein (b) (4)	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'Jan 2014'	System	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '2014'	System	13 Sep 2020 04:43:12

**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	13 Sep 2020 04:43:12



**US3162007**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	System	13 Sep 2020 04:43:12

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '18:11'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '27 Jul 2020 18:11'	System	28 Jul 2020 14:41:59

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '64.5' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59
DataPoint set to visible.	(b) (4) System	28 Jul 2020 01:54:36

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '113.2' lb	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59
DataPoint set to visible.	(b) (4) System	28 Jul 2020 01:54:36

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
Amendment Manager: User entered '19.17065'	System	16 Sep 2020 23:37:09
User entered '19.2'	System	28 Jul 2020 14:41:59
DataPoint set to visible.	System	28 Jul 2020 01:54:36



**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'kg/m2'	System	28 Jul 2020 14:41:59
DataPoint set to visible.	System	28 Jul 2020 01:54:36

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 02:46:51
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'updated' (Site from DM).	Jourdan Manfred (b) (4)	03 Sep 2020 00:28:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 00:28:25
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:51:24
User entered '97.3' F	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:27:07
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' answered with 'Updated.' (Site from DM).	Cynthia Kunakom (b) (4)	24 Sep 2020 17:02:44
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	24 Sep 2020 17:02:38
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:56:46
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:28:25
User entered '87'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'bpm'	System	28 Jul 2020 14:41:59

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:28:25
User entered '14'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'breaths/min'	System	28 Jul 2020 14:41:59



US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:28:25
User entered '110'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'mmHg'	System	28 Jul 2020 14:41:59

US3162007

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:28:25
User entered '61'	Jared Bradshaw (b) (4)	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'mmHg'	System	28 Jul 2020 14:41:59

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41

**US3162007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41

**US3162007**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:42:13

US3162007

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 13:43:31
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 04:20:17
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:42:13
	(b) (4)	



**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

US3162007

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:26:31

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Surgically sterile (SURGICALLY STERILE)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'un UNK 1999'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05

**US3162007**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:31**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:05



US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

[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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:43:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 14:43:44
User entered 'No (N)' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:44
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:43:37
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

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**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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37



US3162007

Folder: Screening

Form: Risk of Exposure

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**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

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 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

US3162007

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:43:37

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:04

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:04

US3162007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:04



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'VISIT1'	System	28 Jul 2020 14:44:04

US3162007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:10

US3162007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:05:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:05:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 01:24:10
User entered '184067' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:10

US3162007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 01:24:10

US3162007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:31

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)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:22

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:31**

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)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:22

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:22

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:31**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:22



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:31**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:44:22

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '64.5' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '133.2' lb	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '64.5' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '133.2' lb	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '18:11'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '27 Jul 2020 18:11'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '97.3' F	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '87'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'bpm'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '14'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'breaths/min'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '110'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '61'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '64.5' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:48:03
User entered '133.2' lb	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 14:46:46



US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:20:28
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		28 Jul 2020 14:46:46
User entered '19:10'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46
	(b) (4)	

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '27 Jul 2020 19:10'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '97.6' F	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '76'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'bpm'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '14'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'breaths/min'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '112'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '65'	Jared Bradshaw (b) (4)	28 Jul 2020 14:46:46

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	28 Jul 2020 14:46:46

US3162007

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:48
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:04



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:48
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:04

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '18:39'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '27 Jul 2020 18:39'	System	28 Jul 2020 01:54:57



US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:54:57

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'ONCE'	System	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 01:54:57

US3162007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:33

US3162007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:33

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '18:33'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:33

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '27 Jul 2020 18:33'	System	28 Jul 2020 14:47:33

US3162007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51



**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

US3162007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '18:37'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '27 Jul 2020 18:37'	System	28 Jul 2020 14:47:51

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

US3162007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:51

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered empty.	System	28 Jul 2020 14:47:51



US3162007

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:47:55

**US3162007**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	28 Jul 2020 14:47:55

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:19:01', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '375532a1-440c-43f5-a8b6-c5997b9a80bc' User entered 'Yes (Y)'	System	28 Jul 2020 03:20:20
	System	28 Jul 2020 03:20:20

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:19:29', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '375532a1-440c-43f5-a8b6-c5997b9a80bc' User entered '97.8'	System	28 Jul 2020 03:20:20
	System	28 Jul 2020 03:20:20

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:19:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '375532a1-440c-43f5-a8b6-c5997b9a80bc' User entered 'No (N)'	System	28 Jul 2020 03:20:20
	System	28 Jul 2020 03:20:20

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:20:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '375532a1-440c-43f5-a8b6-c5997b9a80bc' User entered '27 Jul 2020 20:20'	System	28 Jul 2020 03:20:20
	System	28 Jul 2020 03:20:20

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 18:59'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 21:29'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:30:47', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1690e397-2821-40d9-ac72-ef1d27739ae0' User entered 'Yes (Y)'	System	28 Jul 2020 14:31:07
	System	28 Jul 2020 14:31:07

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:30:56', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1690e397-2821-40d9-ac72-ef1d27739ae0' User entered '97.1'	System	28 Jul 2020 14:31:07
	System	28 Jul 2020 14:31:07

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1690e397-2821-40d9-ac72-ef1d27739ae0' User entered 'No (N)'	System	28 Jul 2020 14:31:07
	System	28 Jul 2020 14:31:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:04', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1690e397-2821-40d9-ac72-ef1d27739ae0' User entered '28 Jul 2020 07:31'	System	28 Jul 2020 14:31:07
	System	28 Jul 2020 14:31:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 22:24'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 2'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:54:57



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 3'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 4'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 5'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 6'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 7'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:25:25', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '05e3978d-4e91-4d56-a81b-3770f4a984f6'	System	28 Jul 2020 03:25:49
User entered 'None (1)'	System	28 Jul 2020 03:25:49



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:25:31', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '05e3978d-4e91-4d56-a81b-3770f4a984f6' User entered 'No (N)'	System	28 Jul 2020 03:25:49
	System	28 Jul 2020 03:25:49

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:25:34', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '05e3978d-4e91-4d56-a81b-3770f4a984f6' User entered 'No (N)'	System	28 Jul 2020 03:25:49
	System	28 Jul 2020 03:25:49

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:25:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '05e3978d-4e91-4d56-a81b-3770f4a984f6'	System	28 Jul 2020 03:25:49
User entered 'None (1)'	System	28 Jul 2020 03:25:49

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:25:44', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '05e3978d-4e91-4d56-a81b-3770f4a984f6' User entered '27 Jul 2020 20:25'	System	28 Jul 2020 03:25:49
	System	28 Jul 2020 03:25:49

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 18:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 21:29'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:12', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6be8e822-5d50-43b6-ace0-430d67c85d79' User entered 'None (1)'	System	28 Jul 2020 14:31:29
	System	28 Jul 2020 14:31:29



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6be8e822-5d50-43b6-ace0-430d67c85d79' User entered 'No (N)'	System	28 Jul 2020 14:31:29
	System	28 Jul 2020 14:31:29

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:19', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6be8e822-5d50-43b6-ace0-430d67c85d79' User entered 'No (N)'	System	28 Jul 2020 14:31:29
	System	28 Jul 2020 14:31:29

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:24', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6be8e822-5d50-43b6-ace0-430d67c85d79' User entered 'None (1)'	System	28 Jul 2020 14:31:29
	System	28 Jul 2020 14:31:29

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:27', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6be8e822-5d50-43b6-ace0-430d67c85d79' User entered '28 Jul 2020 07:31'	System	28 Jul 2020 14:31:29
	System	28 Jul 2020 14:31:29

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 22:24'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 2'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 3'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 4'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 5'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 6'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 7'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:23:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'None (0)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:21:34', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a'	System	28 Jul 2020 03:23:19
User entered 'No interference with activity (1)'	System	28 Jul 2020 03:23:19

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:21:52', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'None (0)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:21:57', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'None (0)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:22:06', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'None (0)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:22:15', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'None (0)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:22:26', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered 'No (N)'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-27T20:23:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '041c1227-ef0c-4b42-b8e2-50c249af9e2a' User entered '27 Jul 2020 20:23'	System	28 Jul 2020 03:23:19
	System	28 Jul 2020 03:23:19

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 18:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 21:29'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:45', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:49', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:52', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:56', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:31:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'None (0)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:32:02', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered 'No (N)'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-07-28T07:32:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5522c046-0b10-4479-aeaa-a14634c05868' User entered '28 Jul 2020 07:32'	System	28 Jul 2020 14:32:07
	System	28 Jul 2020 14:32:07

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '27 Jul 2020 22:24'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 2'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 3'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 4'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:54:57



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 5'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 6'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 7'	System	28 Jul 2020 01:54:57



US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:54:57

US3162007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:54:57

**US3162007**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:47:11

US3162007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '03 Aug 2020' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	10 Nov 2020 17:14:58
User entered '3 Aug 2020'	Jared Bradshaw (b) (4)	05 Aug 2020 04:47:11

**US3162007**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:47:11

US3162007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:47:11

US3162007

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:47:36

**US3162007**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	05 Aug 2020 04:47:36



**US3162007**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:17:00

**US3162007**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
User entered '10 Aug 2020'	Jared Bradshaw (b) (4)	12 Aug 2020 05:17:00

**US3162007**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:17:00

US3162007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
User entered empty.	Jared Bradshaw (b) (4)	12 Aug 2020 05:17:00

**US3162007**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:17:23

**US3162007**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	12 Aug 2020 05:17:23

**US3162007**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 04:05:51

**US3162007**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '17 Aug 2020'	Jared Bradshaw (b) (4)	18 Aug 2020 04:05:51



**US3162007**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	18 Aug 2020 04:05:51

US3162007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	18 Aug 2020 04:05:51

US3162007

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 04:05:56

**US3162007**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	18 Aug 2020 04:05:56

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:20:17

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:20:17

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:20:17

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'VISIT2'	System	02 Sep 2020 04:20:17



US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '11:55'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '31 Aug 2020 11:55'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '97.5' F	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26



US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 22:53:56
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Sep 2020 22:53:56
User entered '88' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:53:56
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 04:23:26
User entered '15'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'bpm'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 22:53:56
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Sep 2020 22:53:56
User entered '15' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:53:56
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 04:23:26
User entered '88'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'breaths/min'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '138'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '84'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	02 Sep 2020 04:23:26



US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '13:39'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '31 Aug 2020 13:39'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '97.1' F	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26



**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '66'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'bpm'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '15'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'breaths/min'	System	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '130'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '78'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:26

US3162007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'mmHg'	System	02 Sep 2020 04:23:26



**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:44

US3162007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 04:24:29
User entered '31 Aug 2020' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	02 Sep 2020 04:24:29
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 04:23:44
User entered '1 Sep 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:23:44

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:05:39

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '13:01'	(b) (4), (b) (6)	31 Aug 2020 20:05:39



**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '31 Aug 2020 13:01'	System	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	31 Aug 2020 20:05:39

US3162007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'ONCE'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:31**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:24:49

US3162007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:24:49

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '12:08'	Jared Bradshaw (b) (4)	02 Sep 2020 04:24:49

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '31 Aug 2020 12:08'	System	02 Sep 2020 04:24:49



**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:26:31**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '31 Aug 2020'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03

US3162007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '12:15'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '31 Aug 2020 12:15'	System	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'No (N)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:03



**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered empty.	System	02 Sep 2020 04:25:03

US3162007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	22 Sep 2020 03:58:48
User entered 'No (N)'	Jared Bradshaw (b) (4)	02 Sep 2020 04:25:06

**US3162007**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered '1'	System	22 Sep 2020 03:58:48
User entered empty.	System	02 Sep 2020 04:25:06

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:40:25', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1972b9b6-8728-449f-adbb-f9a1d2569906' User entered 'Yes (Y)'	System	31 Aug 2020 20:47:37
	System	31 Aug 2020 20:47:37

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:40:41', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1972b9b6-8728-449f-adbb-f9a1d2569906' User entered '97.1'	System	31 Aug 2020 20:47:37
	System	31 Aug 2020 20:47:37

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:41:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1972b9b6-8728-449f-adbb-f9a1d2569906' User entered 'No (N)'	System	31 Aug 2020 20:47:37
	System	31 Aug 2020 20:47:37

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:41:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '1972b9b6-8728-449f-adbb-f9a1d2569906' User entered '31 Aug 2020 13:41'	System	31 Aug 2020 20:47:37
	System	31 Aug 2020 20:47:37



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 13:21'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 15:51'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:44:43', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'eba4dbe3-3755-4846-ab0c-e34b3ea96037' User entered 'No (N)'	System	01 Sep 2020 15:45:18
	System	01 Sep 2020 15:45:18

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:44:49', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'eba4dbe3-3755-4846-ab0c-e34b3ea96037'	System	01 Sep 2020 15:45:18
User entered 'No (N)'	System	01 Sep 2020 15:45:18

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:45:14', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'eba4dbe3-3755-4846-ab0c-e34b3ea96037' User entered '01 Sep 2020 08:45'	System	01 Sep 2020 15:45:18
	System	01 Sep 2020 15:45:18

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 16:46'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:05:39



US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 2'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:05:39



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 3'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-02T20:03:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '8c07c869-080c-4d53-95cb-6f57bc770cbb' User entered 'No (N)'	System	03 Sep 2020 03:04:12
	System	03 Sep 2020 03:04:12

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-02T20:03:48', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '8c07c869-080c-4d53-95cb-6f57bc770cbb' User entered 'No (N)'	System	03 Sep 2020 03:04:12
	System	03 Sep 2020 03:04:12

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-02T20:04:09', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '8c07c869-080c-4d53-95cb-6f57bc770cbb' User entered '02 Sep 2020 20:04'	System	03 Sep 2020 03:04:12
	System	03 Sep 2020 03:04:12

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 4'	System	31 Aug 2020 20:05:39



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:55:50', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a8b26b25-51e5-4880-b13f-f6c801407b6e' User entered 'Yes (Y)'	System	03 Sep 2020 23:56:25
	System	03 Sep 2020 23:56:25

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:06', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a8b26b25-51e5-4880-b13f-f6c801407b6e' User entered '98.4'	System	03 Sep 2020 23:56:25
	System	03 Sep 2020 23:56:25

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:12', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a8b26b25-51e5-4880-b13f-f6c801407b6e' User entered 'No (N)'	System	03 Sep 2020 23:56:25
	System	03 Sep 2020 23:56:25

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:23', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a8b26b25-51e5-4880-b13f-f6c801407b6e' User entered '03 Sep 2020 16:56'	System	03 Sep 2020 23:56:25
	System	03 Sep 2020 23:56:25

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 5'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:13', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'fb3a76e5-74e1-4e32-ac91-642acc4637dc' User entered 'Yes (Y)'	System	05 Sep 2020 05:04:34
	System	05 Sep 2020 05:04:34



US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:23', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'fb3a76e5-74e1-4e32-ac91-642acc4637dc' User entered '98.2'	System	05 Sep 2020 05:04:34
	System	05 Sep 2020 05:04:34

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:27', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'fb3a76e5-74e1-4e32-ac91-642acc4637dc' User entered 'No (N)'	System	05 Sep 2020 05:04:34
	System	05 Sep 2020 05:04:34

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:31', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'fb3a76e5-74e1-4e32-ac91-642acc4637dc' User entered '04 Sep 2020 22:04'	System	05 Sep 2020 05:04:34
	System	05 Sep 2020 05:04:34

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 6'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:56:22', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '65aac00f-dbd0-48c4-9ec0-8617fa64c65d' User entered 'Yes (Y)'	System	06 Sep 2020 16:57:13
	System	06 Sep 2020 16:57:13

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:56:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '65aac00f-dbd0-48c4-9ec0-8617fa64c65d' User entered '98.7'	System	06 Sep 2020 16:57:13
	System	06 Sep 2020 16:57:13



US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:56:55', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '65aac00f-dbd0-48c4-9ec0-8617fa64c65d' User entered 'No (N)'	System	06 Sep 2020 16:57:13
	System	06 Sep 2020 16:57:13

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:57:09', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '65aac00f-dbd0-48c4-9ec0-8617fa64c65d' User entered '06 Sep 2020 09:57'	System	06 Sep 2020 16:57:13
	System	06 Sep 2020 16:57:13

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 7'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:34:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b706a657-9ee4-4344-a5cc-fdd2ffe668cb' User entered 'Yes (Y)'	System	07 Sep 2020 14:36:04
	System	07 Sep 2020 14:36:04

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:35:19', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b706a657-9ee4-4344-a5cc-fdd2ffe668cb' User entered '98.6'	System	07 Sep 2020 14:36:04
	System	07 Sep 2020 14:36:04

US3162007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:35:44', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b706a657-9ee4-4344-a5cc-fdd2ffe668cb' User entered 'No (N)'	System	07 Sep 2020 14:36:04
	System	07 Sep 2020 14:36:04



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:35:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b706a657-9ee4-4344-a5cc-fdd2ffe668cb' User entered '07 Sep 2020 07:35'	System	07 Sep 2020 14:36:04
	System	07 Sep 2020 14:36:04

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:41:35', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a67409c8-5c90-4e8c-9e12-45b14558d1ba' User entered 'None (1)'	System	31 Aug 2020 20:47:52
	System	31 Aug 2020 20:47:52

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:41:44', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a67409c8-5c90-4e8c-9e12-45b14558d1ba' User entered 'No (N)'	System	31 Aug 2020 20:47:52
	System	31 Aug 2020 20:47:52

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:41:53', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a67409c8-5c90-4e8c-9e12-45b14558d1ba' User entered 'No (N)'	System	31 Aug 2020 20:47:52
	System	31 Aug 2020 20:47:52

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:42:30', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a67409c8-5c90-4e8c-9e12-45b14558d1ba' User entered 'None (1)'	System	31 Aug 2020 20:47:52
	System	31 Aug 2020 20:47:52



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T13:43:01', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a67409c8-5c90-4e8c-9e12-45b14558d1ba' User entered '31 Aug 2020 13:43'	System	31 Aug 2020 20:47:52
	System	31 Aug 2020 20:47:52

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 13:21'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 15:51'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:50:55', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85'	System	01 Sep 2020 15:51:04
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 15:51:04

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:46:57', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85'	System	01 Sep 2020 15:51:04
User entered 'No (N)'	System	01 Sep 2020 15:51:04

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:48:08', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85' User entered 'Yes (Y)'	System	01 Sep 2020 15:51:04
	System	01 Sep 2020 15:51:04

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:50:38', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85' User entered '40'	System	01 Sep 2020 15:51:04
	System	01 Sep 2020 15:51:04



US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:50:45', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85'	System	01 Sep 2020 15:51:04
User entered 'None (1)'	System	01 Sep 2020 15:51:04

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-01T08:51:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'b90f0bab-b27e-4729-9adc-e47bd243bc85'	System	01 Sep 2020 15:51:04
User entered '01 Sep 2020 08:51'	System	01 Sep 2020 15:51:04

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 16:46'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 2'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 3'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:05:39



US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 4'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:57:42', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered 'None (1)'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:58:08', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered 'No (N)'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:58:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered 'Yes (Y)'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T17:00:25', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered '40'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T17:00:31', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered 'None (1)'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T17:01:07', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '290bebc9-26a0-48ee-b803-44de7b1634e0' User entered '03 Sep 2020 17:01'	System	04 Sep 2020 00:01:10
	System	04 Sep 2020 00:01:10

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:05:39



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 5'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered 'None (1)'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:43', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered 'No (N)'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:04:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered 'Yes (Y)'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:31', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered '30'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered 'None (1)'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:36', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7ec5519a-0a82-4920-9b67-7fd26d00605d' User entered '04 Sep 2020 22:05'	System	05 Sep 2020 05:05:38
	System	05 Sep 2020 05:05:38



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 6'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:57:22', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '36333163-3ef4-48ad-8620-dfa1745110cc' User entered 'None (1)'	System	06 Sep 2020 16:58:06
	System	06 Sep 2020 16:58:06

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:57:26', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '36333163-3ef4-48ad-8620-dfa1745110cc' User entered 'No (N)'	System	06 Sep 2020 16:58:06
	System	06 Sep 2020 16:58:06

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:57:53', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '36333163-3ef4-48ad-8620-dfa1745110cc' User entered 'No (N)'	System	06 Sep 2020 16:58:06
	System	06 Sep 2020 16:58:06

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:57:56', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '36333163-3ef4-48ad-8620-dfa1745110cc' User entered 'None (1)'	System	06 Sep 2020 16:58:06
	System	06 Sep 2020 16:58:06

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:58:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '36333163-3ef4-48ad-8620-dfa1745110cc' User entered '06 Sep 2020 09:58'	System	06 Sep 2020 16:58:06
	System	06 Sep 2020 16:58:06



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 7'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:36:12', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '00b24d81-fe46-46af-a377-db4652a1191b' User entered 'None (1)'	System	07 Sep 2020 14:36:48
	System	07 Sep 2020 14:36:48

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:36:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '00b24d81-fe46-46af-a377-db4652a1191b' User entered 'No (N)'	System	07 Sep 2020 14:36:48
	System	07 Sep 2020 14:36:48

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:36:22', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '00b24d81-fe46-46af-a377-db4652a1191b' User entered 'No (N)'	System	07 Sep 2020 14:36:48
	System	07 Sep 2020 14:36:48

US3162007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:36:26', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '00b24d81-fe46-46af-a377-db4652a1191b' User entered 'None (1)'	System	07 Sep 2020 14:36:48
	System	07 Sep 2020 14:36:48

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-07T07:36:43', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '00b24d81-fe46-46af-a377-db4652a1191b' User entered '07 Sep 2020 07:36'	System	07 Sep 2020 14:36:48
	System	07 Sep 2020 14:36:48



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:45:13', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'None (0)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:46:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48'	System	31 Aug 2020 22:47:59
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:47:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:46:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'None (0)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:46:20', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'None (0)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:46:32', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'None (0)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:46:48', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'None (0)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:47:12', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered 'No (N)'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-08-31T15:47:55', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '846a6882-aace-4102-a8c5-67913594ed48' User entered '31 Aug 2020 15:47'	System	31 Aug 2020 22:47:59
	System	31 Aug 2020 22:47:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 13:21'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 15:51'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '31 Aug 2020 16:46'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:05:39



US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 2'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 3'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 4'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:32', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:35', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:50', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:56:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:57:01', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:57:03', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'None (0)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:57:10', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered 'No (N)'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-03T16:57:25', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'bc36530d-425a-4c3b-9fcc-15dabce5fc13' User entered '03 Sep 2020 16:57'	System	03 Sep 2020 23:57:29
	System	03 Sep 2020 23:57:29

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:05:39



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 5'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:41', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:43', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:44', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:45', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:47', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'None (0)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59



US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:51', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered 'No (N)'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-04T22:05:54', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '57a9ece4-c84d-4b0e-90c4-a21dd7d4df9d' User entered '04 Sep 2020 22:05'	System	05 Sep 2020 05:05:59
	System	05 Sep 2020 05:05:59

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 6'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:17', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:22', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:27', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39



US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:30', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:45', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'None (0)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T09:59:52', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered 'No (N)'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (322199EC-95B8-4778-A0C1-34E0D98C70DA)', Time: '2020-09-06T10:00:32', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0832ee70-7acb-44a4-86c3-a086b00cd886' User entered '06 Sep 2020 10:00'	System	06 Sep 2020 17:00:39
	System	06 Sep 2020 17:00:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	31 Aug 2020 20:05:39
User entered 'Day 7'	System	31 Aug 2020 20:05:39



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36

US3162007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36



**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:05:39

**US3162007**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:12:41

US3162007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 17:26:43
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed correct.' (Site from System).	Cynthia Kunakom (b) (4)	22 Sep 2020 14:14:16
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 14:12:41
User entered '4 Sep 2020'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:12:41

**US3162007**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:12:41

US3162007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Cynthia Kunakom (b) (4)	22 Sep 2020 14:12:41

US3162007

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:00

**US3162007**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	22 Sep 2020 14:13:00



**US3162007**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:37

US3162007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 17:26:52
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed correct.' (Site from System).	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:56
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 14:13:37
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:37

**US3162007**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:37

US3162007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Cynthia Kunakom (b) (4)	22 Sep 2020 14:13:37

US3162007

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:14:02

**US3162007**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	22 Sep 2020 14:14:02

**US3162007**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:04

US3162007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 17:26:59
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed. Date correct.' (Site from System).	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:33
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 14:19:04
User entered '18 Sep 2020'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:04



**US3162007**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:04

US3162007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:04

US3162007

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	22 Sep 2020 14:19:49

**US3162007**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	22 Sep 2020 14:19:49

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:02

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:02

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:02

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered 'VISIT3'	System	28 Sep 2020 15:28:02



US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '10:33'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered '25 Sep 2020 10:33'	System	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '36.7' C	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '68'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29



**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered 'bpm'	System	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '14'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered 'breaths/min'	System	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '126'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered 'mmHg'	System	28 Sep 2020 15:28:29

US3162007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '72'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered 'mmHg'	System	28 Sep 2020 15:28:29

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38



**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38

US3162007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:47

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:28:47

US3162007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:29:10

US3162007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:29:10

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered '11:23'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:29:10

**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:00:38
User entered '25 Sep 2020 11:23'	System	28 Sep 2020 15:29:10

US3162007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:29:16



**US3162007**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	System	28 Sep 2020 15:29:16

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 64'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-09-29T10:25:27', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6e6366b6-2fa7-4565-b7f6-052529631569'	System	29 Sep 2020 17:26:04
User entered 'No (N)'	System	29 Sep 2020 17:26:04

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-09-29T10:25:40', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6e6366b6-2fa7-4565-b7f6-052529631569'	System	29 Sep 2020 17:26:04
User entered 'No (N)'	System	29 Sep 2020 17:26:04

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-09-29T10:25:59', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '6e6366b6-2fa7-4565-b7f6-052529631569' User entered '29 Sep 2020 10:25:59'	System	29 Sep 2020 17:26:04
	System	29 Sep 2020 17:26:04

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '26 Sep 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '30 Sep 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 71'	System	28 Jul 2020 01:54:57



**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-04T10:19:51', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a28c9558-936e-4e63-a476-1c6c56745a97'	System	04 Oct 2020 17:20:17
User entered 'No (N)'	System	04 Oct 2020 17:20:17

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-04T10:19:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a28c9558-936e-4e63-a476-1c6c56745a97'	System	04 Oct 2020 17:20:17
User entered 'No (N)'	System	04 Oct 2020 17:20:17

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-04T10:20:13', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'a28c9558-936e-4e63-a476-1c6c56745a97' User entered '04 Oct 2020 10:20:13'	System	04 Oct 2020 17:20:17
	System	04 Oct 2020 17:20:17

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '03 Oct 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '07 Oct 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 78'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-12T12:31:07', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '076f31c1-b816-4091-8380-aba5ffeb6840'	System	12 Oct 2020 19:31:25
User entered 'No (N)'	System	12 Oct 2020 19:31:25

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-12T12:31:11', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '076f31c1-b816-4091-8380-aba5ffeb6840'	System	12 Oct 2020 19:31:25
User entered 'No (N)'	System	12 Oct 2020 19:31:25



**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-12T12:31:23', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '076f31c1-b816-4091-8380-aba5ffeb6840' User entered '12 Oct 2020 12:31:23'	System	12 Oct 2020 19:31:25
	System	12 Oct 2020 19:31:25

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '10 Oct 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '14 Oct 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 92'	System	28 Jul 2020 01:54:57

US3162007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-26T13:06:06', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd086dc91-d7da-4846-8c56-7753afefec35'	System	26 Oct 2020 20:06:31
User entered 'No (N)'	System	26 Oct 2020 20:06:31

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-26T13:06:13', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd086dc91-d7da-4846-8c56-7753afefec35'	System	26 Oct 2020 20:06:31
User entered 'No (N)'	System	26 Oct 2020 20:06:31

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-26T13:06:27', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd086dc91-d7da-4846-8c56-7753afefec35' User entered '26 Oct 2020 13:06:27'	System	26 Oct 2020 20:06:31
	System	26 Oct 2020 20:06:31

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '24 Oct 2020 00:01'	System	28 Jul 2020 01:54:57



**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '28 Oct 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 99'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-31T08:25:58', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '46c83e60-ffc6-4edd-8a3c-cded9fdf3324'	System	31 Oct 2020 15:26:24
User entered 'No (N)'	System	31 Oct 2020 15:26:24

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-31T08:26:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '46c83e60-ffc6-4edd-8a3c-cded9fdf3324'	System	31 Oct 2020 15:26:24
User entered 'No (N)'	System	31 Oct 2020 15:26:24

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD73AAD7-C1E4-49B4-8C95-83F84BB28B52)', Time: '2020-10-31T08:26:21', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '46c83e60-ffc6-4edd-8a3c-cded9fdf3324' User entered '31 Oct 2020 08:26:21'	System	31 Oct 2020 15:26:24
	System	31 Oct 2020 15:26:24

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '31 Oct 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '04 Nov 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 106'	System	28 Jul 2020 01:54:57



**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-10T14:36:47', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '12a95bd0-9d33-45f1-a315-cfe7f3eb91c7'	System	10 Nov 2020 22:37:28
User entered 'No (N)'	System	10 Nov 2020 22:37:28

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-10T14:36:56', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '12a95bd0-9d33-45f1-a315-cfe7f3eb91c7'	System	10 Nov 2020 22:37:28
User entered 'No (N)'	System	10 Nov 2020 22:37:28

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-10T14:37:26', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '12a95bd0-9d33-45f1-a315-cfe7f3eb91c7'	System	10 Nov 2020 22:37:28
User entered '10 Nov 2020 14:37:26'	System	10 Nov 2020 22:37:28

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '07 Nov 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '11 Nov 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered 'Day 113'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-16T12:44:38', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '87a5f738-edf0-4d4f-8729-3f1c2421e403'	System	16 Nov 2020 20:45:09
User entered 'No (N)'	System	16 Nov 2020 20:45:09

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-16T12:44:43', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '87a5f738-edf0-4d4f-8729-3f1c2421e403'	System	16 Nov 2020 20:45:09
User entered 'No (N)'	System	16 Nov 2020 20:45:09



**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-16T12:45:02', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '87a5f738-edf0-4d4f-8729-3f1c2421e403'	System	16 Nov 2020 20:45:09
User entered '16 Nov 2020 12:45:02'	System	16 Nov 2020 20:45:09

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '14 Nov 2020 00:01'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:36
Data entry locked.	System	28 Jul 2020 01:54:57
User entered '18 Nov 2020 23:59'	System	28 Jul 2020 01:54:57

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:18:41

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:18:41

**US3162007**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-27T11:23:13', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f6e506c2-714c-4daf-8691-d4bad38b8c1a' User entered 'No (N)'	System	27 Nov 2020 19:23:28



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-27T11:23:18', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f6e506c2-714c-4daf-8691-d4bad38b8c1a'	System	27 Nov 2020 19:23:28
User entered 'No (N)'	System	27 Nov 2020 19:23:28

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-11-27T11:23:26', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f6e506c2-714c-4daf-8691-d4bad38b8c1a' User entered '27 Nov 2020 11:23:26'	System	27 Nov 2020 19:23:28
	System	27 Nov 2020 19:23:28

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-02T08:31:29', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '18c55c52-ec10-467b-933b-2b462c14c55f' User entered 'No (N)'	System	02 Dec 2020 16:31:44
	System	02 Dec 2020 16:31:44

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-02T08:31:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '18c55c52-ec10-467b-933b-2b462c14c55f' User entered 'No (N)'	System	02 Dec 2020 16:31:44
	System	02 Dec 2020 16:31:44

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-02T08:31:41', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '18c55c52-ec10-467b-933b-2b462c14c55f' User entered '02 Dec 2020 08:31:41'	System	02 Dec 2020 16:31:44
	System	02 Dec 2020 16:31:44



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-12T22:01:02', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd55beccf-1253-43ab-a87b-526dc319e829'	System	13 Dec 2020 06:01:17
User entered 'No (N)'	System	13 Dec 2020 06:01:17

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-12T22:01:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd55beccf-1253-43ab-a87b-526dc319e829'	System	13 Dec 2020 06:01:17
User entered 'No (N)'	System	13 Dec 2020 06:01:17

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-12T22:01:09', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'd55beccf-1253-43ab-a87b-526dc319e829'	System	13 Dec 2020 06:01:17
User entered '12 Dec 2020 22:01:09'	System	13 Dec 2020 06:01:17

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-16T07:36:15', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '93517cfd-edd8-4e8a-af11-3807eaa419f9' User entered 'No (N)'	System	16 Dec 2020 15:36:44
	System	16 Dec 2020 15:36:44

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-16T07:36:20', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '93517cfd-edd8-4e8a-af11-3807eaa419f9' User entered 'No (N)'	System	16 Dec 2020 15:36:44

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-16T07:36:39', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '93517cfd-edd8-4e8a-af11-3807eaa419f9' User entered '16 Dec 2020 07:36:39'	System	16 Dec 2020 15:36:44
	System	16 Dec 2020 15:36:44

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-25T17:39:01', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'dbec0a20-efd3-4fdc-8186-44885cd5c75c' User entered 'No (N)'	System	26 Dec 2020 00:39:19
	System	26 Dec 2020 00:39:19



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-25T17:39:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'dbec0a20-efd3-4fdc-8186-44885cd5c75c' User entered 'No (N)'	System	26 Dec 2020 00:39:19

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-25T17:39:16', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'dbec0a20-efd3-4fdc-8186-44885cd5c75c' User entered '25 Dec 2020 17:39:16'	System	26 Dec 2020 00:39:19

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-30T08:55:50', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '984c1971-0c58-4b63-adaa-b8f721af9444'	System	30 Dec 2020 16:56:04
User entered 'No (N)'	System	30 Dec 2020 16:56:04

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-30T08:55:54', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '984c1971-0c58-4b63-adaa-b8f721af9444' User entered 'No (N)'	System	30 Dec 2020 16:56:04
	System	30 Dec 2020 16:56:04

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2020-12-30T08:56:01', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '984c1971-0c58-4b63-adaa-b8f721af9444' User entered '30 Dec 2020 08:56:01'	System	30 Dec 2020 16:56:04
	System	30 Dec 2020 16:56:04



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-06T07:45:33', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '61a26d43-22c9-422e-ada9-c10c54889a51'	System	06 Jan 2021 15:45:48
User entered 'No (N)'	System	06 Jan 2021 15:45:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-06T07:45:37', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '61a26d43-22c9-422e-ada9-c10c54889a51'	System	06 Jan 2021 15:45:48
User entered 'No (N)'	System	06 Jan 2021 15:45:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-06T07:45:45', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '61a26d43-22c9-422e-ada9-c10c54889a51' User entered '06 Jan 2021 07:45:45'	System	06 Jan 2021 15:45:48
	System	06 Jan 2021 15:45:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-13T08:59:59', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5400a584-deb2-46bf-b428-853f87d25c21' User entered 'No (N)'	System	13 Jan 2021 17:00:13
	System	13 Jan 2021 17:00:13

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-13T09:00:02', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5400a584-deb2-46bf-b428-853f87d25c21' User entered 'No (N)'	System	13 Jan 2021 17:00:13
	System	13 Jan 2021 17:00:13

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-13T09:00:07', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '5400a584-deb2-46bf-b428-853f87d25c21' User entered '13 Jan 2021 09:00:07'	System	13 Jan 2021 17:00:13
	System	13 Jan 2021 17:00:13

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-22T15:47:05', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0583981b-9a35-43ee-8f18-05a1c38c8779'	System	22 Jan 2021 23:47:24
User entered 'No (N)'	System	22 Jan 2021 23:47:24



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-22T15:47:10', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0583981b-9a35-43ee-8f18-05a1c38c8779'	System	22 Jan 2021 23:47:24
User entered 'No (N)'	System	22 Jan 2021 23:47:24

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-22T15:47:19', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '0583981b-9a35-43ee-8f18-05a1c38c8779' User entered '22 Jan 2021 15:47:19'	System	22 Jan 2021 23:47:24
	System	22 Jan 2021 23:47:24

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-27T08:01:39', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7846df7b-a39b-401f-b6ba-5a7c20b55f47'	System	27 Jan 2021 16:01:56
User entered 'No (N)'	System	27 Jan 2021 16:01:56

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-27T08:01:46', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7846df7b-a39b-401f-b6ba-5a7c20b55f47'	System	27 Jan 2021 16:01:56
User entered 'No (N)'	System	27 Jan 2021 16:01:56

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-01-27T08:01:53', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7846df7b-a39b-401f-b6ba-5a7c20b55f47' User entered '27 Jan 2021 08:01:53'	System	27 Jan 2021 16:01:56
	System	27 Jan 2021 16:01:56



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-03T07:44:39', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '03927a26-733c-40cf-8bb9-e84aacfc1689' User entered 'No (N)'	System	03 Feb 2021 15:44:57
	System	03 Feb 2021 15:44:57

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-03T07:44:46', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '03927a26-733c-40cf-8bb9-e84aacfc1689' User entered 'No (N)'	System	03 Feb 2021 15:44:57
	System	03 Feb 2021 15:44:57

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-03T07:44:52', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '03927a26-733c-40cf-8bb9-e84aacfc1689' User entered '03 Feb 2021 07:44:52'	System	03 Feb 2021 15:44:57
	System	03 Feb 2021 15:44:57

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-11T11:45:46', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'af020541-3a5e-43d3-b44e-e267f91d1ad4'	System	11 Feb 2021 19:46:01
User entered 'No (N)'	System	11 Feb 2021 19:46:01

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-11T11:45:53', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'af020541-3a5e-43d3-b44e-e267f91d1ad4'	System	11 Feb 2021 19:46:01
User entered 'No (N)'	System	11 Feb 2021 19:46:01

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-11T11:45:59', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'af020541-3a5e-43d3-b44e-e267f91d1ad4' User entered '11 Feb 2021 11:45:59'	System	11 Feb 2021 19:46:01
	System	11 Feb 2021 19:46:01

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-17T08:08:34', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '792afe1a-0aeb-46d5-8d0b-af2bd2db0d85'	System	17 Feb 2021 16:56:53
User entered 'No (N)'	System	17 Feb 2021 16:56:53



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-17T08:56:44', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '792afe1a-0aeb-46d5-8d0b-af2bd2db0d85' User entered 'No (N)'	System	17 Feb 2021 16:56:53
	System	17 Feb 2021 16:56:53

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-17T08:56:50', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '792afe1a-0aeb-46d5-8d0b-af2bd2db0d85' User entered '17 Feb 2021 08:56:50'	System	17 Feb 2021 16:56:53
	System	17 Feb 2021 16:56:53

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-24T07:54:25-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '667ef62a-4ae1-4fd2-b3f6-5635462fe17f' User entered 'No (N)'	System	24 Feb 2021 15:54:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-24T07:54:29-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '667ef62a-4ae1-4fd2-b3f6-5635462fe17f' User entered 'No (N)'	System	24 Feb 2021 15:54:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-02-24T07:54:33-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '667ef62a-4ae1-4fd2-b3f6-5635462fe17f' User entered '24 Feb 2021 15:54:33'	System	24 Feb 2021 15:54:38
	System	24 Feb 2021 15:54:38



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:08:31-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c8cde05b-96ff-45ee-bfe0-24409a8f1aea'	System	03 Mar 2021 16:23:09
User entered 'No (N)'	System	03 Mar 2021 16:23:09

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:08:39-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c8cde05b-96ff-45ee-bfe0-24409a8f1aea'	System	03 Mar 2021 16:23:09
User entered 'Yes (Y)'	System	03 Mar 2021 16:23:09

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:22:31-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c8cde05b-96ff-45ee-bfe0-24409a8f1aea'	System	03 Mar 2021 16:23:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Mar 2021 16:23:09

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:22:57-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c8cde05b-96ff-45ee-bfe0-24409a8f1aea'	System	03 Mar 2021 16:23:09
User entered '03 Mar 2021 08:22:57'	System	03 Mar 2021 16:23:09

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-12T10:36:43-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '672bb2e1-d639-4c9a-8a5f-19b93c51c9fa'	System	12 Mar 2021 18:38:38
User entered 'No (N)'	System	12 Mar 2021 18:38:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-12T10:36:51-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '672bb2e1-d639-4c9a-8a5f-19b93c51c9fa'	System	12 Mar 2021 18:38:38
User entered 'Yes (Y)'	System	12 Mar 2021 18:38:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-12T10:37:13-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '672bb2e1-d639-4c9a-8a5f-19b93c51c9fa'	System	12 Mar 2021 18:38:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Mar 2021 18:38:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-12T10:38:24-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '672bb2e1-d639-4c9a-8a5f-19b93c51c9fa'	System	12 Mar 2021 18:38:38
User entered '12 Mar 2021 10:38:24'	System	12 Mar 2021 18:38:38

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-17T10:32:44-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7d9e947a-6d99-4432-a0b1-e5f0c0f19dfb'	System	17 Mar 2021 17:33:05
User entered 'No (N)'	System	17 Mar 2021 17:33:05

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-17T10:32:55-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7d9e947a-6d99-4432-a0b1-e5f0c0f19dfb'	System	17 Mar 2021 17:33:05
User entered 'No (N)'	System	17 Mar 2021 17:33:05

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-17T10:33:00-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '7d9e947a-6d99-4432-a0b1-e5f0c0f19dfb'	System	17 Mar 2021 17:33:05
User entered '17 Mar 2021 10:33:00'	System	17 Mar 2021 17:33:05

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-24T10:48:37-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '2fa8ac8a-4f38-401a-a357-f235bd746ed8'	System	24 Mar 2021 17:48:53
User entered 'No (N)'	System	24 Mar 2021 17:48:53



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-24T10:48:45-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '2fa8ac8a-4f38-401a-a357-f235bd746ed8'	System	24 Mar 2021 17:48:53
User entered 'No (N)'	System	24 Mar 2021 17:48:53

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-24T10:48:50-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '2fa8ac8a-4f38-401a-a357-f235bd746ed8' User entered '24 Mar 2021 10:48:50'	System	24 Mar 2021 17:48:53
	System	24 Mar 2021 17:48:53

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-31T09:01:24-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f769118d-719c-4933-9965-54a0a69ecdcd' User entered 'No (N)'	System	31 Mar 2021 16:04:31
	System	31 Mar 2021 16:04:31

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-31T09:01:29-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f769118d-719c-4933-9965-54a0a69ecdcd' User entered 'No (N)'	System	31 Mar 2021 16:04:31

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-31T09:01:34-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'f769118d-719c-4933-9965-54a0a69ecdcd' User entered '31 Mar 2021 09:01:34'	System	31 Mar 2021 16:04:31
	System	31 Mar 2021 16:04:31



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-07T08:39:05-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '10259071-8a5d-468e-aa0f-a596c041a961'	System	07 Apr 2021 15:39:59
User entered 'No (N)'	System	07 Apr 2021 15:39:59

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-07T08:39:43-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '10259071-8a5d-468e-aa0f-a596c041a961'	System	07 Apr 2021 15:39:59
User entered 'No (N)'	System	07 Apr 2021 15:39:59

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-07T08:39:51-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '10259071-8a5d-468e-aa0f-a596c041a961'	System	07 Apr 2021 15:39:59
User entered '07 Apr 2021 08:39:51'	System	07 Apr 2021 15:39:59

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-15T09:06:48-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'ff2b0660-cdb4-49fd-a84e-28d4ad1d20bc'	System	15 Apr 2021 16:13:48
User entered 'No (N)'	System	15 Apr 2021 16:13:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-15T09:06:56-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'ff2b0660-cdb4-49fd-a84e-28d4ad1d20bc'	System	15 Apr 2021 16:13:48
User entered 'No (N)'	System	15 Apr 2021 16:13:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-15T09:07:01-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'ff2b0660-cdb4-49fd-a84e-28d4ad1d20bc'	System	15 Apr 2021 16:13:48
User entered '15 Apr 2021 09:07:01'	System	15 Apr 2021 16:13:48

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-21T07:54:57-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '3d450375-210e-41ae-955e-30492a2ff340'	System	21 Apr 2021 14:55:18
User entered 'No (N)'	System	21 Apr 2021 14:55:18



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-21T07:55:10-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '3d450375-210e-41ae-955e-30492a2ff340'	System	21 Apr 2021 14:55:18
User entered 'No (N)'	System	21 Apr 2021 14:55:18

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-21T07:55:15-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '3d450375-210e-41ae-955e-30492a2ff340'	System	21 Apr 2021 14:55:18
User entered '21 Apr 2021 07:55:15'	System	21 Apr 2021 14:55:18

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-28T08:08:00-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c0b04601-48cc-4d46-835b-769ea46dc060'	System	29 Apr 2021 02:21:31
User entered 'No (N)'	System	29 Apr 2021 02:21:31

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

Have you been exposed to someone with 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 (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-28T08:08:07-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c0b04601-48cc-4d46-835b-769ea46dc060'	System	29 Apr 2021 02:21:31
User entered 'No (N)'	System	29 Apr 2021 02:21:31

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-04-28T08:08:10-07:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: 'c0b04601-48cc-4d46-835b-769ea46dc060'	System	29 Apr 2021 02:21:31
User entered '28 Apr 2021 08:08:10'	System	29 Apr 2021 02:21:31



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:18:41



**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:18:41

**US3162007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:41
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:18:41



US3162007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:26:31

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 17:31:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:23:54-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '8cb19f6e-e727-4815-be99-7ae067749ba4'	System	03 Mar 2021 16:24:07
User entered 'No (N)'	System	03 Mar 2021 16:24:07

**US3162007**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:31:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E24501DD-FB45-4219-8041-364C2140D029)', Time: '2021-03-03T08:24:04-08:00', User OID: 'PatientReportedOutcome (US3162007)', ODM File OID: '8cb19f6e-e727-4815-be99-7ae067749ba4' User entered '03 Mar 2021 08:24:04'	System	03 Mar 2021 16:24:07
	System	03 Mar 2021 16:24:07

**US3162007**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
	(b) (4), (b) (6)	
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 16:27:54
	(b) (4)	

US3162007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Oct 2020 12:02:36
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed correct.' (Site from System).	Cynthia Kunakom (b) (4)	20 Oct 2020 16:28:35
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Oct 2020 16:27:54
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4)	20 Oct 2020 16:27:54

**US3162007**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 03:59:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	20 Oct 2020 16:27:54

US3162007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
	(b) (4), (b) (6)	
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 16:27:54
	(b) (4)	

**US3162007**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
	(b) (4), (b) (6)	
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:14:26
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 16:28:42
	(b) (4)	

**US3162007**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:52
User entered 'I'	(b) (4), (b) (6) System	20 Oct 2020 16:28:42



**US3162007**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Dec 2020 19:04:04

**US3162007**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered '27 Nov 2020'	Tiffany Williams (b) (4) (b) (4)	01 Dec 2020 19:04:04

**US3162007**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	01 Dec 2020 19:04:04

US3162007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Dec 2020 19:04:04

US3162007

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Dec 2020 19:04:13

**US3162007**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User entered 'I'	System	01 Dec 2020 19:04:13

**US3162007**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	30 Dec 2020 23:08:00

**US3162007**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered '29 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	30 Dec 2020 23:08:00



**US3162007**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	30 Dec 2020 23:08:00

US3162007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered empty.	Tiffany Williams (b) (4) (b) (4)	30 Dec 2020 23:08:00

**US3162007**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	30 Dec 2020 23:08:06

**US3162007**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User entered 'I'	System	30 Dec 2020 23:08:06

**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:14:26
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Feb 2021 19:58:24

**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:14:26
User entered '28 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	01 Feb 2021 19:58:24

**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:14:26
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	01 Feb 2021 19:58:24

**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:14:26
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Feb 2021 19:58:24



**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Feb 2021 19:58:30

**US3162007**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:55
User entered 'I'	System	01 Feb 2021 19:58:30

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 20:33:06

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '19 Feb 2021'	(b) (4) Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 20:33:06

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[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 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 20:33:06

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'VISIT4'	(b) (4), (b) (6) System	22 Feb 2021 20:33:06

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46



**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:39:46

US3162007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46



**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:39:46

US3162007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:39:46

US3162007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:39:46

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
	(b) (4), (b) (6)	

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
	(b) (4), (b) (6)	

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'No (N)'	(b) (4) Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 20:33:16



**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
	(b) (4), (b) (6)	
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:25
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	22 Feb 2021 20:33:16
	(b) (4)	

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:44:02

US3162007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '19 Feb 2021'	(b) (4) Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:44:02

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '11:15'	(b) (4) Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:44:02

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered '19 Feb 2021 11:15'	(b) (4), (b) (6) System	05 Mar 2021 00:44:02

US3162007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User signature succeeded.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	(b) (4) Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 20:33:24

**US3162007**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:11:41
User entered 'I'	(b) (4), (b) (6) System	22 Feb 2021 20:33:24

**US3162007**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:15:47



US3162007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '29 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:15:47

US3162007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Apr 2021 21:15:47

**US3162007**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:15:47

US3162007

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:16:05

**US3162007**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 21:16:05

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:12:59

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:12:59

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:12:59



**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 00:12:59

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:25
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:02:04

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:25
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:02:04

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:38:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:38:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18



US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:38:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:38:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:13:18

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	25 Feb 2021 05:38:59
User entered 'I'	System	17 Feb 2021 00:13:18

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	25 Feb 2021 05:38:59
User entered 'I'	System	17 Feb 2021 00:13:18

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '64.5' in	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '113.2' lb	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '64.5' in	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '113.2' lb	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01



**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '17:05'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered '12 Feb 2021 17:05'	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '98.4' F	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01



**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '72'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered 'bpm'	System	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '14'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered 'breaths/min'	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '128'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered 'mmHg'	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '72'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered 'mmHg'	System	17 Feb 2021 00:18:01



US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '64.5' in	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:31**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '113.2' lb	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User closed query 'Please verify if they were not done vs. not applicable. I am uncertain if N/A is an option. If not done, please say why they were not done in your query response. Thank you.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 00:40:41
Query 'Please verify if they were not done vs. not applicable. I am uncertain if N/A is an option. If not done, please say why they were not done in your query response. Thank you.' answered with 'Correct as is. Site inadvertently entered in EDC that subject was previously randomized to placebo and received mRNA during OL Visit. Subject was previously randomized to mRNA and received both doses and didn't receive any additional doses during OL Visit. EDC updated to reflect correction' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 05:42:10
User opened query 'Please verify if they were not done vs. not applicable. I am uncertain if N/A is an option. If not done, please say why they were not done in your query response. Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 16:42:23
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01



US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	17 Feb 2021 00:18:01

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	17 Feb 2021 00:18:01



US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered empty.	System	17 Feb 2021 00:18:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:31**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:11

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered empty.	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:11

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:37

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 05:50:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'Correct as is. Accession # 1F60118. results are shown as received and reported. Report generated on 28FEB2021' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:06:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:59:56
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:37

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '17:10'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:37

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered '12 Feb 2021 17:10'	System	17 Feb 2021 00:18:37



**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:31**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:55

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:26:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '12 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:55

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:31**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered '17:10'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:18:55

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:31**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered '12 Feb 2021 17:10'	System	17 Feb 2021 00:18:55

US3162007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 16:53:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	17 Feb 2021 00:19:01

**US3162007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:09
User entered '1'	System	17 Feb 2021 00:19:01

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:26:31**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:09:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:47:01

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:26:31**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:28:52
User entered	System	04 Aug 2020 12:28:42
'USA-US074-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	04 Aug 2020 12:28:42



US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:27:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:27:53
Data point term sent to Coder	System	08 Sep 2020 20:08:02
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	08 Sep 2020 20:07:35
Coding entries removed.	Cynthia Kunakom (b) (4) (b) (4)	08 Sep 2020 20:07:35
User entered 'Mild CEREBROVASCULAR ACCIDENT' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	08 Sep 2020 20:07:35
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:54:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 01:54:13
Data point term sent to Coder	System	04 Aug 2020 01:53:37
User entered 'Cerebrovascular Accident'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:07:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 20:07:44
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	08 Sep 2020 20:07:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:07:35
User entered empty.	Cynthia Kunakom (b) (4)	08 Sep 2020 20:07:35
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

US3162007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:56:03
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	31 Aug 2020 20:05:39
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '30 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User closed query 'Per CDM: Start time should be left blank unless the AE started within 24 hours of dosing. Please refer to CCGs. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:44:49
Query 'Per CDM: Start time should be left blank unless the AE started within 24 hours of dosing. Please refer to CCGs. Please update accordingly. ' answered with 'updated- time left blank as instructed' (Site from DM).	Jared Bradshaw (b) (4)	15 Aug 2020 01:39:52
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 22:36:44
DataPoint Un-verified.	Jared Bradshaw (b) (4)	12 Aug 2020 22:36:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	12 Aug 2020 22:36:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
	(b) (4), (b) (6)	05 Aug 2020 18:31:05
User opened query 'Per CDM: Start time should be left blank unless the AE started within 24 hours of dosing. Please refer to CCGs. Please update accordingly. ' (Site from DM).		(b)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:24:45
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'data is correct as entered' (Site from System).	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:51
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 01:53:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Aug 2020 01:53:16
User entered 'UN:UN' (non-conformant).	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:16
	(b) (4)	

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**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:26:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:36:44
User entered '30 Jul 2020 UN:UN' (non-conformant).	System	04 Aug 2020 01:53:16

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:40:32
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Sep 2020 03:24:14
DataPoint Un-verified.	Judith Kirstein (b) (4)	12 Sep 2020 03:24:14
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	12 Sep 2020 03:24:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Sep 2020 03:23:42
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:57:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:57:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16



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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User closed query 'PV Query: Please clarify the end date of the event. The query response indicates 31Jul2020 as the end date, however, 01Aug2020 is entered as the end date in EDC. Please confirm which is correct and update the EDC if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:35:09
Query 'PV Query: Please clarify the end date of the event. The query response indicates 31Jul2020 as the end date, however, 01Aug2020 is entered as the end date in EDC. Please confirm which is correct and update the EDC if applicable.' answered with 'corrected date' (Site from Safety).	Judith Kirstein (b) (4)	19 Sep 2020 01:53:48
DataPoint Un-verified.	Judith Kirstein (b) (4)	19 Sep 2020 01:53:37
User entered '31 Jul 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	19 Sep 2020 01:53:37
User opened query 'PV Query: Please clarify the end date of the event. The query response indicates 31Jul2020 as the end date, however, 01Aug2020 is entered as the end date in EDC. Please confirm which is correct and update the EDC if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 14:47:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:40:34
User entered '1 Aug 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	12 Sep 2020 03:32:16
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	12 Sep 2020 03:26:12
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	12 Sep 2020 03:26:12

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	12 Sep 2020 03:23:42
	Judith Kirstein (b) (4)	12 Sep 2020 03:23:42
	(b) (4)	
User entered '31 Jul 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	12 Sep 2020 03:23:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
DataPoint Un-verified.	Jared Bradshaw (b) (4)	15 Aug 2020 01:57:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	15 Aug 2020 01:57:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '31 Jul 2020'	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:16
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User closed query 'Per CDM: End time should be left blank unless the AE ended within 24 hours of dosing. Refer to CCGs for additional clarification as needed. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:49:29
Query 'Per CDM: End time should be left blank unless the AE ended within 24 hours of dosing. Refer to CCGs for additional clarification as needed. Please update accordingly' answered with 'updated- left blank as instructed' (Site from DM).	Jared Bradshaw (b) (4)	15 Aug 2020 01:40:08
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 22:36:44
DataPoint Un-verified.	Jared Bradshaw (b) (4)	12 Aug 2020 22:36:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	12 Aug 2020 22:36:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
	(b) (4), (b) (6)	05 Aug 2020 18:33:59
User opened query 'Per CDM: End time should be left blank unless the AE ended within 24 hours of dosing. Refer to CCGs for additional clarification as needed. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Aug 2020 18:33:36
Query 'Per CDM: Start time should be left blank unless the AE ended within 24 hours of dosing. Refer to CCGs for additional clarification as needed. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	05 Aug 2020 18:33:24
User opened query 'Per CDM: Start time should be left blank unless the AE ended within 24 hours of dosing. Refer to CCGs for additional clarification as needed. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Aug 2020 18:32:18
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:32:18
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'data is correct as entered' (Site from System).	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:53
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 01:53:16
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Aug 2020 01:53:16
User entered 'UN:UN' (non-conformant).	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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**Form: Adverse Events (1)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 22:36:44
User entered '31 Jul 2020 UN:UN' (non-conformant).	System	04 Aug 2020 01:53:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:26:31

Severity

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:40:37
User closed query 'PV Query: Was the event considered life-threatening? If no, please consider updating the event intensity to Grade 3 (required hospitalization).' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 20:34:43
Query 'PV Query: Was the event considered life-threatening? If no, please consider updating the event intensity to Grade 3 (required hospitalization).' answered with 'Updated event intensity to Grade 3' (Site from Safety).	Judith Kirstein (b) (4)	12 Sep 2020 03:20:04
DataPoint Un-verified.	Judith Kirstein (b) (4)	12 Sep 2020 03:19:37
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Per Query Resolution	Judith Kirstein (b) (4)	12 Sep 2020 03:19:37
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User opened query 'PV Query: Was the event considered life-threatening? If no, please consider updating the event intensity to Grade 3 (required hospitalization).' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 17:46:42
User closed query 'PV Query: The event intensity is Grade 4 which requires life-threatening consequences and/or urgent intervention indicated. Since the subject was not treated while hospitalized please assess if event met criteria of Grade 4. If no, please update appropriately. ' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 16:48:59
Query 'PV Query: The event intensity is Grade 4 which requires life-threatening consequences and/or urgent intervention indicated. Since the subject was not treated while hospitalized please assess if event met criteria of Grade 4. If no, please update appropriately. ' answered with 'Severity updated to grade 4' (Site from Safety).	Cynthia Kunakom (b) (4) (b) (4)	24 Aug 2020 19:19:35

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[Severity](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event intensity is Grade 4 which requires life-threatening consequences and/or urgent intervention indicated. Since the subject was not treated while hospitalized please assess if event met criteria of Grade 4. If no, please update appropriately. ' (Site from Safety).	(b) (4), (b) (6)	18 Aug 2020 18:26:08
User closed query 'PV Query: Please consider updating CTCAE grade from grade 1 to 3 as the subject required hospitalization.' (Site from Safety).	(b) (4), (b) (6)	17 Aug 2020 16:50:34
Query 'PV Query: Please consider updating CTCAE grade from grade 1 to 3 as the subject required hospitalization.' answered with 'PI assessed as grade 4' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:43
DataPoint Un-verified.	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:26
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:26
User opened query 'PV Query: Please consider updating CTCAE grade from grade 1 to 3 as the subject required hospitalization.' (Site from Safety).	(b) (4), (b) (6)	06 Aug 2020 17:49:33
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:16

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16



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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '30 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'None (NONE)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User closed query 'The subject has started two new medications as a result of the AE. This answer should be unchecked. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:38:46
	(b) (4), (b) (6)	04 Sep 2020 00:34:54
Query 'The subject has started two new medications as a result of the AE. This answer should be unchecked. Thank you.' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:50
	(b) (4)	
	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:26
	(b) (4)	
User entered '0' reason for change: Data Entry Error DataPoint Verified.	Jared Bradshaw (b) (4)	15 Aug 2020 01:42:26
	(b) (4)	
	(b) (4), (b) (6)	05 Aug 2020 22:14:23
	(b) (4), (b) (6)	05 Aug 2020 22:13:54
User opened query 'The subject has started two new medications as a result of the AE. This answer should be unchecked. Thank you.' (Site from CRA). User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Aug 2020 01:54:08
User entered '1' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	04 Aug 2020 01:54:08
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Aug 2020 01:53:16
User entered '0'	Jared Bradshaw (b) (4)	04 Aug 2020 01:53:16
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'The subject has started two new medications as a result of the AE. This answer should be checked. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 00:38:49 04 Sep 2020 00:34:54
Query 'The subject has started two new medications as a result of the AE. This answer should be checked. Thank you.' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4) Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:42:55 15 Aug 2020 01:42:26 15 Aug 2020 01:42:26
User entered '1' reason for change: Data Entry Error DataPoint Verified.	Jared Bradshaw (b) (4) (b) (4), (b) (6)	15 Aug 2020 01:42:26 05 Aug 2020 22:14:23
User opened query 'The subject has started two new medications as a result of the AE. This answer should be checked. Thank you.' (Site from CRA). User entered '0'	(b) (4), (b) (6) Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 22:14:07 04 Aug 2020 01:53:16

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Query 'Per DM CLR: Please note that there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:39:24
User opened query 'Per DM CLR: Please note that there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 01:55:38
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16



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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:40:01
User closed query 'PV Query: Please provide the end date and updated outcome for the event, when available. Please do not respond to this query until this information is available. ' (Site from Safety). Query 'PV Query: Please provide the end date and updated outcome for the event, when available. Please do not respond to this query until this information is available. ' answered with 'End date 31Jul20. No sequelae' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 20:34:56
DataPoint Un-verified.	Judith Kirstein (b) (4)	12 Sep 2020 03:27:19
	Judith Kirstein (b) (4)	12 Sep 2020 03:26:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	12 Sep 2020 03:26:12
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User opened query 'PV Query: Please provide the end date and updated outcome for the event, when available. Please do not respond to this query until this information is available. ' (Site from Safety).	(b) (4), (b) (6)	18 Aug 2020 18:26:35
DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:57:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:57:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Per DM CLR: SAE Narrative = CPK WAS 227U/L ON 30JUL20. However, this information was not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). Query 'Per DM CLR: SAE Narrative = CPK WAS 227U/L ON 30JUL20. However, this information was not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Entered' (Site from DM).	(b) (4), (b) (6) Judith Kirstein (b) (4)	20 Oct 2020 06:25:54 15 Oct 2020 00:11:24
User opened query 'Per DM CLR: SAE Narrative = CPK WAS 227U/L ON 30JUL20. However, this information was not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 01:55:49 16 Sep 2020 00:40:23
User closed query 'PV Query: Please provide results of COVID-19 testing and date performed when available. (Please place response in SAE narrative section.)' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 15:06:24
User closed query 'PV Query: Please provide vital sign values with date(s) from the hospitalization (i.e., heart rate, blood pressure). If not available please state so. (Please place response in SAE narrative section.)' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 15:06:21
User closed query 'PV Query: Please provide further details regarding the clinical course of the event until resolution, as applicable. (Please place response in SAE narrative section.)' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 15:06:17
User closed query 'PV Query: Please provide reference range and units for the CPK laboratory test, if available. (Please place response in SAE narrative section.)' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 15:06:15

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide vital sign values with date(s) from the hospitalization (i.e., heart rate, blood pressure). If not available please state so. (Please place response in SAE narrative section.)' answered with 'SEE NARRATIVE SECTION' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:35:22
Query 'PV Query: Please provide further details regarding the clinical course of the event until resolution, as applicable. (Please place response in SAE narrative section.)' answered with 'SEE NARRATIVE SECTION' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:35:12
Query 'PV Query: Please provide reference range and units for the CPK laboratory test, if available. (Please place response in SAE narrative section.)' answered with 'SEE NARRATIVE SECTION' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:34:58
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:34:02
User entered 'DAY 8 SAFETY CALL DONE. SUBJECT REPORTED BEING HOSPITALIZED FROM 30JUL TO 31 JUL 2020 FOR A MILD CEREBROVASCULAR ACCIDENT. NEW CON MEDS NOTED. SAE REPORTED TO SPONSOR. SUBJECT WILL CONTINUE IN STUDY. AS PER SPONSOR QUERY: CPK WAS 227U/L ON 30JUL20. VS WERE AS FOLLOWS ON 30JUL20: BP 129/68 HR 61 CLINICAL COURSE: SUBJECT UNDERWENT DUPLEX CAROTID SCAN WHICH WAS NEGATIVE, BRAIN CT SHOWED SMALL ACUTE INFARCT IN RIGHT OCCIPITAL LOBE. SUBJECT WAS SENT HOME ON ASPIRIN AND ATORVASTATIN AS NOTED IN CON MEDS.' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:34:02
Query 'PV Query: Please provide results of COVID-19 testing and date performed when available. (Please place response in SAE narrative section.)' answered with 'Test performed 31July20 and was negative' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 03:16:49

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of COVID-19 testing and date performed when available. (Please place response in SAE narrative section.)' (Site from Safety).	(b) (4), (b) (6)	18 Aug 2020 18:28:39
User opened query 'PV Query: Please provide vital sign values with date(s) from the hospitalization (i.e., heart rate, blood pressure). If not available please state so. (Please place response in SAE narrative section.)' (Site from Safety).		18 Aug 2020 18:28:16
User opened query 'PV Query: Please provide further details regarding the clinical course of the event until resolution, as applicable. (Please place response in SAE narrative section.)' (Site from Safety).		18 Aug 2020 18:27:51
User opened query 'PV Query: Please provide reference range and units for the CPK laboratory test, if available. (Please place response in SAE narrative section.)' (Site from Safety).		18 Aug 2020 18:27:26
User closed query 'PV Query: Please confirm if the patient's symptoms had resolved at resolution of the event.' (Site from Safety).		17 Aug 2020 22:03:57
User closed query 'PV Query: Was a cardiac workup done? Was an EKG performed?' (Site from Safety).		17 Aug 2020 22:03:54
User closed query 'PV Query: Did the patient ever experience any neurological symptoms associated or not with these cardiac conditions (i.e. dizziness, loss of consciousness, consciousness impairment, neurological deficits, etc.)' (Site from Safety).		17 Aug 2020 22:03:49
User closed query 'PV Query: Please provide specifics regarding medical history of bradycardia and hypertension. Was the patient on any medications for these conditions?' (Site from Safety).		17 Aug 2020 22:03:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and any therapies (PT, OT, ST). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		17 Aug 2020 22:03:37
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		17 Aug 2020 22:03:32

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EAB) (1725)

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please confirm.' (Site from Safety).	(b) (4), (b) (6)	17 Aug 2020 22:03:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. CT, MRI). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Aug 2020 22:03:23
User closed query 'PV Query: Please provide the initial signs and symptoms of cerebrovascular accident exhibited by the patient.' (Site from Safety).	(b) (4), (b) (6)	17 Aug 2020 22:02:09
Query 'PV Query: Was a cardiac workup done? Was an EKG performed?' answered with 'CPK lab was ran with a result of 227. No EKG was performed. An echocardiogram was to be done later as an outpatient procedure. ' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 02:34:24
Query 'PV Query: Did the patient ever experience any neurological symptoms associated or not with these cardiac conditions (i.e. dizziness, loss of consciousness, consciousness impairment, neurological deficits, etc.)' answered with 'patient complained of acute memory loss. ' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 02:05:37
Query 'PV Query: Please provide specifics regarding medical history of bradycardia and hypertension. Was the patient on any medications for these conditions?' answered with 'Patient was on Lisinopril for Hypertension(found in eCRF) and not taking anything for bradycardia ' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 02:04:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and any therapies (PT, OT, ST). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Only treatment given was aspirin and atorvastatin which are in concomitant medication eCRF' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 02:03:55

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please confirm.' answered with 'all con meds entered into con med eCRF' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 02:03:01
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Yes, swab was performed, but results were not available before patient was discharged and did not come in medical records that we received.' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 01:59:07
Query 'PV Query: Please confirm if the patient's symptoms had resolved at resolution of the event.' answered with 'data updated. Symptoms remain ongoing.' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 01:57:34
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. CT, MRI). Please include units and reference ranges if applicable.' answered with 'MRI of brain and brain stem done, with and without contrast, found a tiny focal restricted diffusion suggested in the right occipital cortex. A CT venogram of the head with and without contrast found no evidence of venous sinus thrombosis. An ultrasound duplex scan bilateral extracranial carotid arteries found no hemodynamically significant carotid stenosis demonstrated bilaterally. Creatinine kinase was 227.' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 01:55:31
Query 'PV Query: Please provide the initial signs and symptoms of cerebrovascular accident exhibited by the patient.' answered with 'Acute memory loss' (Site from Safety).	Jared Bradshaw (b) (4)	15 Aug 2020 01:51:20
User opened query 'PV Query: Was a cardiac workup done? Was an EKG performed?' (Site from Safety).	(b) (4), (b) (6)	06 Aug 2020 17:50:13
User opened query 'PV Query: Did the patient ever experience any neurological symptoms associated or not with these cardiac conditions (i.e. dizziness, loss of consciousness, consciousness impairment, neurological deficits, etc.)' (Site from Safety).		06 Aug 2020 17:50:03

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide specifics regarding medical history of bradycardia and hypertension. Was the patient on any medications for these conditions?' (Site from Safety).	(b) (4), (b) (6)	06 Aug 2020 17:49:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and any therapies (PT, OT, ST). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		06 Aug 2020 17:49:14
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please confirm.' (Site from Safety).		06 Aug 2020 17:48:56
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		06 Aug 2020 17:48:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. CT, MRI). Please include units and reference ranges if applicable.' (Site from Safety).		06 Aug 2020 17:47:59
User opened query 'PV Query: Please confirm if the patient's symptoms had resolved at resolution of the event.' (Site from Safety).		06 Aug 2020 17:47:49
User opened query 'PV Query: Please provide the initial signs and symptoms of cerebrovascular accident exhibited by the patient.' (Site from Safety).		06 Aug 2020 17:47:38
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:14:23
User entered 'Day 8 safety call done. Subject reported being hospitalized from 30Jul to 31 Jul 2020 for a mild cerebrovascular accident. New con meds noted. SAE reported to sponsor. Subject will continue in study.'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:53:16



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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

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**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Occipital headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:52
Data point term sent to Coder	System	12 Feb 2021 21:07:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Occipital headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 05:20:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 05:20:19
Data point term sent to Coder	System	12 Aug 2020 05:20:00
User entered 'occipital headache'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**Form: Adverse Events (2)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	02 Sep 2020 14:49:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**Form: Adverse Events (2)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	02 Sep 2020 14:49:36
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39



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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:56:09
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	31 Aug 2020 20:05:39
User entered '30 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Aug 2020 02:07:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 02:07:54
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:07:54
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'unknown per source.' (Site from System).	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 05:19:20
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Aug 2020 05:19:20
User entered 'un:un' (non-conformant).	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User entered empty.	System	15 Aug 2020 02:07:54
User entered '30 Jul 2020 UN:UN' (non-conformant).	System	12 Aug 2020 05:19:20

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	02 Sep 2020 14:49:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '01 Aug 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	02 Sep 2020 14:49:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User entered empty.	System	12 Aug 2020 05:19:20

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20



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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:31**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20



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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'None (NONE)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Aug 2020 02:07:54
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Aug 2020 05:19:20
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '1' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:07:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20



**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	02 Sep 2020 14:49:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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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)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:19:20

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
User entered '1'	System	02 Sep 2020 14:49:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:36
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:53:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:53:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
Data point term sent to Coder	System	12 Feb 2021 21:07:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4) (b) (4)	12 Feb 2021 21:07:19
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 08:53:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 08:53:08
Data point term sent to Coder	System	26 Nov 2020 05:54:52
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4) (b) (4)	26 Nov 2020 05:54:07
Coding entries removed.	Judith Kirstein (b) (4) (b) (4) (b) (4)	26 Nov 2020 05:54:07
User entered 'URTICARIA TRUNK, INTERMITTENT' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4) (b) (4)	26 Nov 2020 05:54:07
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User closed query 'Subject Medical Records note "memory loss", please verify if this should be added into EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:26:25



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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:26:31
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 16:45:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	23 Sep 2020 16:45:44
Data point term sent to Coder	System	23 Sep 2020 04:54:19
Query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Judith Kirstein (b) (4)	23 Sep 2020 04:54:19
' answered with 'Corrected' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Sep 2020 04:54:01
	(b) (4)	
Coding entries removed.	Judith Kirstein (b) (4)	23 Sep 2020 04:54:01
	(b) (4)	
User entered 'URTICARIA TRUNK' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Sep 2020 04:54:01
	(b) (4)	
User opened query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	23 Sep 2020 04:49:26
' (Site from DM).		
Query 'Subject Medical Records note "memory loss", please verify if this should be added into EDC.	Judith Kirstein (b) (4)	19 Sep 2020 02:11:48
Thank you.' answered with 'memory loss added as AE' (Site from CRA).	(b) (4)	

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Subject Medical Records note "memory loss", please verify if this should be added into EDC. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:23:17
	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 05:22:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 05:22:19
	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 05:21:00
User entered 'urticaria'	Jared Bradshaw (b) (4)	12 Aug 2020 05:21:00
	(b) (4)	

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 04:54:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 04:54:32
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Sep 2020 04:54:32
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 04:54:01
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Sep 2020 04:54:01
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:56:15
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	31 Aug 2020 20:05:39
User entered '06 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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Form: Adverse Events (3)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Aug 2020 02:08:16
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	15 Aug 2020 02:08:16
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Aug 2020 05:21:00
User entered '20:00'	Jared Bradshaw (b) (4)	12 Aug 2020 05:21:00
	(b) (4)	

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**Form: Adverse Events (3)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 02:08:16
User entered '06 Aug 2020 20:00'	System	12 Aug 2020 05:21:00



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:05:47
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'RENAMED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	26 Nov 2020 05:54:16
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:22:26
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 05:21:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00



US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00



US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'None (NONE)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

US3162007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00



**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:34:54
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:00

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:05:44
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:05:39

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Amnesia, LLT: Memory loss - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 21:22:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 21:22:58
Data point term sent to Coder	System	12 Feb 2021 21:07:23
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Amnesia, LLT: Memory loss - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:08:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:08:46
Data point term sent to Coder	System	19 Sep 2020 02:07:51
User entered 'MEMORY LOSS'	Judith Kirstein (b) (4)	19 Sep 2020 02:07:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32



US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '29 Jul 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:40:27
User entered '30 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32



US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32



US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'None (NONE)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Sep 2020 02:11:26
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:11:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Sep 2020 02:07:32
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32



US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

US3162007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:26:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 23:27:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Sep 2020 02:07:32

**US3162007**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Sep 2020 02:07:32

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:26:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:05:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:56:13

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:14:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:57
Data point term sent to Coder	System	12 Feb 2021 21:07:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:01
User closed query 'Aspirin has come and gone from the source and EDC. Please review progress notes and update the source and EDC as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 23:25:16



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:09:41
Query 'Aspirin has come and gone from the source and EDC. Please review progress notes and update the source and EDC as applicable. Thank you.' answered with 'Initial aspirin got removed. This is new med.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:30:05
Data point term sent to Coder	System	04 Sep 2020 20:29:51
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'Aspirin' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Aspirin has come and gone from the source and EDC. Please review progress notes and update the source and EDC as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Sep 2020 00:44:56
Data point term sent to Coder	System	03 Sep 2020 19:33:42
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 13:40:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 13:40:05
Data point term sent to Coder	System	04 Aug 2020 01:59:38
User entered 'Aspirin'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:03
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:05
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'Mild Cerebrovascular accident' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Prophylaxis for Cerebrovascular Accident'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:08
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered '81' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '81'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'mg (mg)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:12
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'once daily (QD)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'Oral (ORAL)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:15
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	04 Sep 2020 20:29:48
User entered '31 Jul 2020' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '1 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:18
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
User entered empty; reason for change New Information	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:07:03
User entered 'No (N)' reason for change: New Information	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:07:03
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:20
User entered '15 Aug 2020' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:07:03
User entered '11 Aug 2020' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:07:03
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:26:22
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:29:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:29:48
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:29:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:33:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:33:22
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 01:59:01



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User entered '1'	System	04 Sep 2020 20:29:48
User entered empty.	System	03 Sep 2020 19:33:22
User entered '1'	System	04 Aug 2020 01:59:01

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User entered '1'	System	04 Sep 2020 20:29:48
User entered empty.	System	03 Sep 2020 19:33:22
User entered '1'	System	04 Aug 2020 01:59:01

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:57:59
User entered '804 (804)'	System	04 Sep 2020 20:29:48
User entered empty.	System	03 Sep 2020 19:33:22
User entered '804 (804)'	System	04 Aug 2020 01:59:01

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
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)	12 Feb 2021 21:22:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:51
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:01
User closed query 'What happened to his medication in the source and EDC?' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 23:27:50
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)	04 Sep 2020 20:32:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:32:38
Data point term sent to Coder	System	04 Sep 2020 20:31:55
Query 'What happened to his medication in the source and EDC?' answered with 'They were deleted at first. They got added 3-SEP-2020.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:32
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'Lisinopril' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User opened query 'What happened to his medication in the source and EDC?' (Site from CRA).	(b) (4), (b) (6)	04 Sep 2020 00:46:46
Data point term sent to Coder	System	03 Sep 2020 19:37:50
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Aug 2020 13:37:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Aug 2020 13:37:05
Data point term sent to Coder	System	04 Aug 2020 02:00:38
User entered 'Atorvastatin'	Jared Bradshaw (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:02
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:04
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'Hypertension' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Prophylaxis for Cerebrovascular Accident'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:06
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered '10' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '40'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:08
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'mg (mg)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'once daily (QD)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:14
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'Oral (ORAL)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:17
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	04 Sep 2020 20:31:17
User entered 'un UNK 2013' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '1 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:19
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:22
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User entered '07 Aug 2020' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:28:24
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:31:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:31:17
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:37:10
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:37:10
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 02:00:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 02:00:17
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:17
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 02:00:08
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User entered '1'	System	04 Sep 2020 20:31:17
User entered empty.	System	03 Sep 2020 19:37:10
User entered '1'	System	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User entered '1'	System	04 Sep 2020 20:31:17
User entered empty.	System	03 Sep 2020 19:37:10
User entered '1'	System	04 Aug 2020 02:00:08

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:18:18
User entered '804 (804)'	System	04 Sep 2020 20:31:17
User entered empty.	System	03 Sep 2020 19:37:10
User entered '804 (804)'	System	04 Aug 2020 02:00:08

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:58
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'What happened to his medication in the source and EDC?' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 23:29:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:11:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:11:43
Query 'What happened to his medication in the source and EDC?' answered with 'They were removed and added again from CRIO. EDC should be up to date now.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:33:03
Data point term sent to Coder	System	04 Sep 2020 20:32:58
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'Atorvastatin' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:32:43
User opened query 'What happened to his medication in the source and EDC?' (Site from CRA).	(b) (4), (b) (6)	04 Sep 2020 00:46:57
Data point term sent to Coder	System	03 Sep 2020 19:32:36
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
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)	05 Aug 2020 04:22:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 04:22:08
Data point term sent to Coder	System	05 Aug 2020 04:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'lisinopril' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:20:29
Data point term sent to Coder	System	05 Aug 2020 03:48:57
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:47:56
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)	05 Aug 2020 03:36:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 03:36:08
Data point term sent to Coder	System	05 Aug 2020 03:34:48
User entered 'Lisinopril'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:19
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:32:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:31:44
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:31:44
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:20:29
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:47:56
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:21
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'mild cerebrovascular accident' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'hypertension' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:47:56
	(b) (4)	
User entered 'hypertension'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:23
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered '40' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered '10' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:47:56
	(b) (4)	
User entered '10'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:25
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'mg (mg)' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'mg (mg)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:47:56
	(b) (4)	
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:27
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'once daily (QD)' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'once daily (QD)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:47:56
	(b) (4)	
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:29
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'Oral (ORAL)' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:48:09
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:48:09
	(b) (4)	
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:31
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	04 Sep 2020 20:32:43
User entered '1 Aug 2020' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:34:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	Jared Bradshaw (b) (4)	05 Aug 2020 04:23:49
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:20:29
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Aug 2020 04:20:29
User entered 'un UNK 2013' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 03:47:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	System	05 Aug 2020 03:47:56
answered by data change (Site from System).		
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Aug 2020 03:47:56
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 03:47:56
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 03:34:06
User entered 'un UNK 2013'	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:33
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:32:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:31:44
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:31:44
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:20:29
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:48:09
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:48:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:35
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:32:43
User entered '8 Aug 2020' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	04 Sep 2020 20:32:43
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 03:34:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 23:29:36
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 20:32:43
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4)	04 Sep 2020 20:32:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:31:44
DataPoint Un-verified.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	03 Sep 2020 19:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 04:20:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 04:20:29
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	05 Aug 2020 04:20:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 03:34:06
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 03:34:06
	(b) (4)	

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:32:43
User entered empty.	System	03 Sep 2020 19:31:44
User entered '1'	System	05 Aug 2020 04:20:29
User entered empty.	System	05 Aug 2020 03:47:56
User entered '1'	System	05 Aug 2020 03:34:06



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:32:43
User entered empty.	System	03 Sep 2020 19:31:44
User entered '1'	System	05 Aug 2020 04:20:29
User entered empty.	System	05 Aug 2020 03:47:56
User entered '1'	System	05 Aug 2020 03:34:06

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:32:43
User entered empty.	System	03 Sep 2020 19:31:44
User entered '804 (804)'	System	05 Aug 2020 04:20:29
User entered empty.	System	05 Aug 2020 03:47:56
User entered '804 (804)'	System	05 Aug 2020 03:34:06

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:55
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 12:24:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 12:24:31
Data point term sent to Coder	System	03 Sep 2020 19:55:54
Coding entries removed.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:55:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:10:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:10:18
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Aug 2020 04:23:19
User entered 'meloxicam'	Jared Bradshaw (b) (4)	05 Aug 2020 04:22:37
	(b) (4)	

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:37:38
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:55:04
User entered 'Osteoarthritis bilateral hands, bilateral knees, neck' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:55:04
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'osteoarthritis bilateral hands, knees, neck'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '7.5'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:34:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:42
answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:22:37
User entered 'un UNK 2016'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:22:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:22:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:34:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:34:24
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
Data point term sent to Coder	System	05 Aug 2020 04:24:21
User entered 'omeprazole'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'acid reflux disease'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '20'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:42:26
DataPoint Un-verified.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:07:47
User entered 'twice daily (BID)' reason for change:	Jared Bradshaw (b) (4)	18 Aug 2020 04:07:47
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:35:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per the CRF, all con meds must be entered. Please fix EDC' (Site from System).	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 04:23:25
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:08:09
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 04:07:47
User entered '1'	System	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 04:23:25

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 04:23:25

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:55
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:12:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:12:18
Data point term sent to Coder	System	12 Aug 2020 05:22:01
User entered 'diphenhydramine'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'urticaria'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '25'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '08 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 05:21:58

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 05:21:58



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 05:21:58

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:48:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:48:10
Data point term sent to Coder	System	15 Aug 2020 02:02:05
User entered 'Methocarbamol'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Occipital Headache'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 18:22:10
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'She took 1/2 of a 750 mg tablet' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	13 Sep 2020 04:37:59
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:03:19
User entered '375'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '30 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '1 Aug 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 19:54:31
User entered '8 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:01:36



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User entered empty.	System	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User entered empty.	System	15 Aug 2020 02:01:36

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:11
User entered empty.	System	15 Aug 2020 02:01:36

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:38:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:38:51
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 02:04:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 02:04:10
Data point term sent to Coder	System	15 Aug 2020 02:03:06
User entered 'Losartan'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Hypertension'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '25'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '8 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 02:02:24

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 02:02:24

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:57
Data point term sent to Coder	System	12 Feb 2021 21:07:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 06:18:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 06:18:21
Data point term sent to Coder	System	18 Aug 2020 04:09:31
User entered 'zyrtec'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'urticaria'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '10'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '11 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 04:08:57

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 04:08:57

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:52
Data point term sent to Coder	System	12 Feb 2021 21:07:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:49:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:49:27
Data point term sent to Coder	System	18 Aug 2020 04:10:32
User entered 'hydrocortisone 2.5% cream'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'urticaria'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 20:17:28
User entered 'QS'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Other (OTHER)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Application' reason for change: Data Entry Error	Judith Kirstein (b) (4)	04 Oct 2020 20:17:28
User entered 'QS'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:36
User closed query 'Source documents note TID, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:15:34
Query 'Source documents note TID, please verify. Thank you.' answered with 'Corrected' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:14
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:02
User entered 'three times daily (TID)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User opened query 'Source documents note TID, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:25:59
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Topical (TOPICAL)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '11 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 23:05:02
User entered '2'	System	18 Aug 2020 04:09:56

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 04:09:56



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 04:09:56

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
Data point term sent to Coder	System	12 Feb 2021 21:07:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Subject received procedures during a hospital stay (MRI, etc) that required contrast injections, please update the doses on the con med page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 23:32:36
Query 'Subject received procedures during a hospital stay (MRI, etc) that required contrast injections, please update the doses on the con med page. Thank you.' answered with 'con meds updated' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 04:04:17
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:27
User opened query 'Subject received procedures during a hospital stay (MRI, etc) that required contrast injections, please update the doses on the con med page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 00:39:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 04:12:22
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 Aug 2020 04:12:22
Data point term sent to Coder	System	18 Aug 2020 04:11:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'vitamin b12'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:31
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:34
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 18:24:04
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 'Medical history updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	13 Sep 2020 04:42:01
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)	10 Sep 2020 05:23:08
User entered 'vitamin b12 deficiency'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:37
User entered '1000'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:41
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:44
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:47
User closed query 'Per hospital medical records, the subject is getting a B12 shot monthly. Please verify if the subject is taking oral supplements or receiving an injection. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 17:16:16
Query 'Per hospital medical records, the subject is getting a B12 shot monthly. Please verify if the subject is taking oral supplements or receiving an injection. Thank you.' answered with 'Oral supplement' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	17 Sep 2020 02:13:40
User opened query 'Per hospital medical records, the subject is getting a B12 shot monthly. Please verify if the subject is taking oral supplements or receiving an injection. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 00:38:10
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:51
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:53
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:16:57
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (6)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:17:00
User entered '05 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:17:03
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:17:06
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:17:10
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:17:13
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 04:10:33

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 04:10:33

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: MAGNETIC RESONANCE IMAGING CONTRAST MEDIA, ATC: PARAMAGNETIC CONTRAST MEDIA, PRODUCT: GADOBUTROL, PRODUCTSYNONYM: GADAVIST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
Data point term sent to Coder	System	12 Feb 2021 21:07:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: MAGNETIC RESONANCE IMAGING CONTRAST MEDIA, ATC: PARAMAGNETIC CONTRAST MEDIA, PRODUCT: GADOBUTROL, PRODUCTSYNONYM: GADAVIST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 07:08:49
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 Sep 2020 07:08:49
Data point term sent to Coder	System	19 Sep 2020 02:14:58
User entered 'Gadavist (contrast for MRI)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Contrast for MRI procedure'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '5'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mL (mL)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once (ONCE)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
	1)	
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Sep 2020 02:14:37
	(b) (4)	

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User entered empty.	System	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User entered empty.	System	19 Sep 2020 02:14:37

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:46:53
User entered empty.	System	19 Sep 2020 02:14:37

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:38:51
Data point term sent to Coder	System	12 Feb 2021 21:07:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:34:43
Data point term sent to Coder	System	19 Sep 2020 02:18:00
User entered 'OMNIPAQUE 350'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'CONTRAST FOR CT VENOGRAM OF HEAD'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '97'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mL (mL)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once (ONCE)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User entered empty.	System	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User entered empty.	System	19 Sep 2020 02:17:54

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:36:12
User entered empty.	System	19 Sep 2020 02:17:54



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:54
Data point term sent to Coder	System	12 Feb 2021 21:07:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:06:41
Data point term sent to Coder	System	10 Nov 2020 23:06:00
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 02:25:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Sep 2020 02:25:38
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	19 Sep 2020 02:25:05
User entered 'PLAVIX'	Judith Kirstein (b) (4)	19 Sep 2020 02:24:38
	(b) (4)	

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:50
User closed query 'Source documents note "prophylaxis", please update data entry. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:15:49
Query 'Source documents note "prophylaxis", please update data entry. Thank you.' answered with 'CHANGED' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:06:09
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:57
User entered 'STROKE PROPHYLAXIS' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 23:05:57
User opened query 'Source documents note "prophylaxis", please update data entry. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:56:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'STROKE PREVENTION'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '75'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '17 Aug 2020'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	19 Sep 2020 02:24:38



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 02:24:38

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 02:24:38

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 02:24:38

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:51
Data point term sent to Coder	System	12 Feb 2021 21:07:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:30:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:30:28
Data point term sent to Coder	System	04 Oct 2020 20:18:43
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 20:17:59
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:19:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Sep 2020 17:19:45
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Sep 2020 15:27:37
User entered 'Triamcinolone 0.1% ointment'	Cynthia Kunakom (b) (4)	28 Sep 2020 15:26:45
	(b) (4)	

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Urticaria on abdomen'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45



US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Other (OTHER)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'application'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:42:12
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'error corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	04 Oct 2020 20:18:08
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	04 Oct 2020 20:17:59
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 10:38:49
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:26:45

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:26:45

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:22:56
Data point term sent to Coder	System	12 Feb 2021 21:07:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:27:48
Data point term sent to Coder	System	28 Sep 2020 15:27:39
User entered 'Prednisone'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Urticaria on abdomen'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '20'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23



**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered '28 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

US3162007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:26:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:47
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User entered '1'	System	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User entered '1'	System	28 Sep 2020 15:27:23

**US3162007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:26:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:48
User entered '804 (804)'	System	28 Sep 2020 15:27:23



US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:26:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:41:12
User closed query 'The subject had several procedures during her hospitalization. Please update answer to "yes". Please verify if the following procedures should be added into EDC: CT Venogram w/contrat, MRI w/contrast, and ECG. Thank you,' (Site from CRA).	(b) (4), (b) (6)	02 Oct 2020 16:41:08
Query 'The subject had several procedures during her hospitalization. Please update answer to "yes". Please verify if the following procedures should be added into EDC: CT Venogram w/contrat, MRI w/contrast, and ECG. Thank you,' answered with 'Procedures listed in C P section' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:53:42
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:31:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:31:01
User opened query 'The subject had several procedures during her hospitalization. Please update answer to "yes". Please verify if the following procedures should be added into EDC: CT Venogram w/contrat, MRI w/contrast, and ECG. Thank you,' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 23:21:28
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:41:13
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:19:59

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:32:11

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Transthoracic echocardiogram'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:32:11

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:32:11

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:32:11

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:35:24

**US3162007**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Ultrasound duplex scan bilateral extracranial carotid arteries'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:35:24

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:35:24



US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:35:24

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered '31 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:36:38

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'CT Venogram of head with and without contrast'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:36:38

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:36:38

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:36:38

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered '30 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:38:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'MRI Brain and Brainstem with and without contrast'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:38:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:38:28



US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:38:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered '24 Aug 2020'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:52:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Cardiac event monitor (Holter)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:52:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:52:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 16:58:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Sep 2020 22:52:28

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:26:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:59:16
User entered '30 Jul 2020'	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 00:10:35

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:26:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:59:16
User entered 'CPK 227'	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 00:10:35

US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:26:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:59:16
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 00:10:35



US3162007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:26:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:59:16
User entered empty.	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 00:10:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered '04/Aug/2020 08:30'	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'I'	(b) (4), (b) (6)	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered '13/Aug/2020 09:03'	System	13 Aug 2020 13:03:34

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 13:03:34

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered '17/Aug/2020 09:03'	System	17 Aug 2020 13:03:53

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:03:24
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 13:03:53

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered '09/Sep/2020 12:43'	System	09 Sep 2020 16:43:01



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 20:03:24
User entered 'I'	(b) (4), (b) (6)	09 Sep 2020 16:43:01

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered '12/Sep/2020 16:03'	System	12 Sep 2020 20:03:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 20:03:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered '15/Sep/2020 11:05'	System	15 Sep 2020 15:05:37

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:35:20
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 15:05:37

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'USA-US074-2020-MRNA-1273-P301000001'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42



**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'Yes (Y)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Aug 2020 12:29:57
User entered 'No (N)'	System	04 Aug 2020 12:28:42

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
User closed query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 00:37:11
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:50
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
Query 'Please verify if you are able to complete the PI name, and address fields noted below.' answered with 'data updated' (Site from CRA).	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:37
User entered 'Judith'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30
User opened query 'Please verify if you are able to complete the PI name, and address fields noted below.' (Site from CRA).	(b) (4), (b) (6)	05 Aug 2020 22:15:59

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Kirstein'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE-USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '264 N Highland Springs Ave Suite 4'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
Query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Aug 2020 00:12:07
User opened query 'per ETRTR: Please complete all missing data entry within this SAE folder, thanks.' (Site from CRA).		06 Aug 2020 00:10:34



US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'Banning'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 00:37:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:04:46
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:14
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:40:14
Amendment Manager: User entered 'CA'	System	14 Sep 2020 21:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:58
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered 'California'	Jared Bradshaw (b) (4)	15 Aug 2020 01:38:30
	(b) (4)	

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 00:32:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Aug 2020 13:03:21
User entered '92220'	Jared Bradshaw (b) (4) (b) (4)	15 Aug 2020 01:38:30

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:31**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:08:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Aug 2020 13:03:20
DataPoint Verified.	(b) (4), (b) (6)	05 Aug 2020 22:18:17
User entered 'US' (non-conformant).	System	04 Aug 2020 12:30:35

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:19
	(b) (4)	
User entered '7'	System	20 Sep 2020 20:35:38
User entered '6'	System	15 Sep 2020 15:05:37
User entered '5'	System	12 Sep 2020 20:03:42
User entered '4'	System	09 Sep 2020 16:43:01
User entered '3'	System	17 Aug 2020 13:03:53
User entered '2'	System	13 Aug 2020 13:03:34
User entered '1'	System	04 Aug 2020 12:30:35

**US3162007**

**Folder: SAE USA-US074-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:26:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:50:30
User entered '20/Sep/2020 16:35'	System	20 Sep 2020 20:35:38

US3162007

Folder: SAE USA-US074-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:26:31

**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.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:50:32
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 20:35:38