

US3162072 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:29:54

All time stamps listed in this document are displayed in GMT

US3162072

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 01:02:57

Generated On: 09 Jun 2021 15:29:54

---

Participant ID

US3162072

---

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

---

---

US3162072

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3162072

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3162072

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Date of Informed Consent (*dd MMM yyyy*) 6 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

US3162072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3162072

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3162072

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

US3162072

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162072

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 1983
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 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

US3162072

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Condition	HYPERLIPDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162072

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	6 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:32 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:32
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	180 lb
BMI ( <i>xxx.x</i> )	25.15740 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)	

US3162072

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

US3162072

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3162072

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

<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>	

US3162072

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	6 AUG 2020
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
------------	--------

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 185048

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 ☒

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Height	ND - Not Done
Weight	ND - Not Done

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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)	6 AUG 2020
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:32
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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)	6 AUG 2020
Time of assessment (00:00-23:59)	16:22 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 16:22
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)	62 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)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 15:47 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 15:47

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

US3162072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 AUG 2020
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	6 AUG 2020 15:35

US3162072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:40	6 AUG 2020 15:40
Nasopharyngeal Swab 2	No		

US3162072

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 16:19

PC Open Date & Time

06 AUG 2020 16:07

PC Close Date & Time

06 AUG 2020 18:37

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.7 °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 AUG 2020 20:34
PC Open Date & Time	06 AUG 2020 19:32
PC Close Date & Time	07 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 20:05

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:50

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

09 AUG 2020 20:56

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

10 AUG 2020 20:50

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 20:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:39

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 16:20

PC Open Date & Time

06 AUG 2020 16:07

PC Close Date & Time

06 AUG 2020 18:37

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**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

06 AUG 2020 20:34

PC Open Date & Time

06 AUG 2020 19:32

PC Close Date & Time

07 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 20:06

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 19:51

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 20:57

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 20:51

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**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

11 AUG 2020 20:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**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

12 AUG 2020 20:39

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**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 ☐

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:21
PC Open Date & Time	06 AUG 2020 16:07
PC Close Date & Time	06 AUG 2020 18:37

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**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 ☐

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:35
PC Open Date & Time	06 AUG 2020 19:32
PC Close Date & Time	07 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

45 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:06
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:51
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:57
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

51 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 20:51
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

53 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**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

55 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:40
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3162072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:15
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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)	3 SEP 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:22
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:46 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:46

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

US3162072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	14:33 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:33

US3162072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:36	3 SEP 2020 14:36
Nasopharyngeal Swab 2	No		

US3162072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**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

03 SEP 2020 15:21

PC Open Date & Time

03 SEP 2020 15:06

PC Close Date & Time

03 SEP 2020 17:36

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**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 97.8 °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	03 SEP 2020 20:26
PC Open Date & Time	03 SEP 2020 18:31
PC Close Date & Time	04 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 19:27

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:29

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

06 SEP 2020 20:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 19:34

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:46

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:10

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:18

PC Open Date & Time

03 SEP 2020 15:06

PC Close Date & Time

03 SEP 2020 17:36

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**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

03 SEP 2020 20:26

PC Open Date & Time

03 SEP 2020 18:31

PC Close Date & Time

04 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:27

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:30

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 19:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**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

08 SEP 2020 21:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**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

09 SEP 2020 20:10

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**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 ☐

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:17
PC Open Date & Time	03 SEP 2020 15:06
PC Close Date & Time	03 SEP 2020 17:36

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**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 ☐

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 20:27
PC Open Date & Time	03 SEP 2020 18:31
PC Close Date & Time	04 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

91 of 2865

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:28
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

93 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:30
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

97 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

99 of 2865

EAB) (1725)

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 21:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**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 ☒

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:10
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:29:54

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3162072

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:29:54

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3162072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	1 OCT 2020
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
------------	--------

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:58 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 13:58
Temperature ( <i>xxx.x</i> )	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 1 OCT 2020

Collection time (00:00-23:59) 14:07 (24 HR)

Collection date and time (derived) 1 OCT 2020 14:07

US3162072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:19

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

<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	08 OCT 2020 18:56:19
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 15 OCT 2020 19:24:02

Patient Cloud Open Date & Time 13 OCT 2020 00:01

Patient Cloud Close Date & Time 17 OCT 2020 23:59

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 09:04:44
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 NOV 2020 08:12:10
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 NOV 2020 08:15:25
Patient Cloud Open Date & Time	10 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
122 of 2865	

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

---

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

---

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

19 NOV 2020 06:28:04

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 15:10:00

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 13:10:20

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

08 DEC 2020 11:07:21

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

14 DEC 2020 14:00:12

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

22 DEC 2020 07:12:13

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 12:26:42
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

<b>TIMEPOINT</b>	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 <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	04 JAN 2021 16:49:19
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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	11 JAN 2021 13:15:56
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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	18 JAN 2021 17:30:14
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

26 JAN 2021 06:58:43

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 11:09:45

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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	09 FEB 2021 12:05:29
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 13:01:06
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

22 FEB 2021 13:00:49

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

01 MAR 2021 15:55:42

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

08 MAR 2021 18:31:35

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAR 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 MAR 2021 08:27:48
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAR 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

05 APR 2021 17:00:18

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

13 APR 2021 09:54:09

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

19 APR 2021 08:55:32

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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

26 APR 2021 12:33:16

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAY 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

31 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 AUG 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 AUG 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 NOV 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
---	-------------------

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 DEC 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 JAN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 FEB 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 FEB 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 MAR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 MAR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAR 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 APR 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 MAY 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 JUN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 JUN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 <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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 JUN 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 JUL 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 JUL 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 AUG 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 AUG 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 AUG 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 SEP 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**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 ☐

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2022 23:59

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

---

US3162072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 OCT 2022 23:59

---

**US3162072**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 15:29:54**

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		08 MAR 2021 18:31:16

US3162072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:45 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 13:45
Temperature ( <i>xxx.x</i> )	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

14:29 (24 HR)

Collection date and time (derived)

2 MAR 2021 14:29

US3162072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3162072**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

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*

**US3162072**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Date of Contact	9 NOV 2020
Time of Contact	09:45
Date and Time of Contact (derived)	9 NOV 2020 09:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	100.3 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

322 of 2865

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.3 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

326 of 2865

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

327 of 2865

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2865

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2865

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Date of Visit 9 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 9 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

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

**Generated On: 09 Jun 2021 15:29:54**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3162072

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 NOV 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3162072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	9 NOV 2020
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
------------	--------

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 NOV 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 11:19
Height (xxx.x)	71 in
Weight (xxx.x)	197.4 lb
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3162072

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

9 NOV 2020

US3162072

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	2 FEB 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3162072

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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

US3162072

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Height	
Weight	
BMI (xxx.x)	

US3162072

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Height	
Weight	
BMI (xxx.x)	
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)	2 FEB 2021
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 09:01
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Height	
Weight	
BMI (xxx.x)	
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)	2 FEB 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 10:15

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

US3162072

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 2 FEB 2021

Collection time (00:00-23:59) 09:02 (24 HR)

Collection date and time (derived) 2 FEB 2021 09:02

US3162072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

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

Collection date (dd MMM yyyy)	2 FEB 2021
-------------------------------	------------

Collection time (00:00 - 23:59)	09:04
---------------------------------	-------

Collection Date and Time (derived)	2 FEB 2021 09:04
------------------------------------	------------------

US3162072

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:03:18

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3162072

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
------------	-------

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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)	2 MAR 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 13:45
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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)	2 MAR 2021
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 16:07
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3162072

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 MAR 2021

What was the treatment time? (00:00-23:59) 15:32 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 15:32

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

US3162072

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162072

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162072

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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

Visit date (dd MMM yyyy)	01 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
------------	-------

US3162072

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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) \_\_\_\_\_

US3162072

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

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.*

US3162072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	01 APR 2021
Collection time ( <i>00:00-23:59</i> )	13:52 (24 HR)
Collection date and time (derived)	01 APR 2021 13:52

US3162072

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 01:02:57

Generated On: 09 Jun 2021 15:29:54

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID

Adverse event

ACUTE VIRAL INFECTION,  
UNSPECIFIED

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)

8 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

369 of 2865

EAB) (1725)

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

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	
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)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID	
Adverse event	ANGINA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

371 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☒  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☐

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐  
Not Recovered/Not Resolved ☐  
Recovered/Resolved ☒  
Recovered/Resolved with Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative SUBJECT HAD EXPERIENCED MILD ANGINA STARTING MID-OCTOBER 2020 BUT DID NOT CONTACT HIS PCP UNTIL IT WORSENER. THIS LED TO HIS HAVING 5VESSEL CORONARY BYPASS SURGERY ON 12MAR2021. SEE AE#3

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 24 Apr 2021 23:00:12

**Generated On: 09 Jun 2021 15:29:54**

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)	

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID	USA-US074-2021-MRNA-1273-P30 1000020
Adverse event	CRESCENDO ANGINA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 FEB 2021
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)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

SUBJECT HAD ONSET OF  
ANGINA IN MID-OCTOBER 2020.  
IT WORSENEED 15FEB BUT HE  
DID NOT SEEK MEDICAL CARE  
UNTIL 04MAR2021, WHEN HE  
HAD TELEMEDICINE VISIT  
WITH PCP. SAW  
CARDIOLOGIST 10MAR21,  
ADMITTED TO ONE HOSPITAL  
WHERE STRESS ECHO SHOWED  
ST SEGMENT DEPRESSION, AND  
CAUSED CHEST PAIN, SO HE  
WAS TRANSFERRED TO  
ANOTHER HOSPITAL WHERE  
CORONARY ANGIOGRAPHY  
SHOWED MULTIVESSEL  
DISEASE, NECESSITATING 5  
VESSEL CORONARY BYPASS  
ON 12MAR21. DURING THAT  
STAY, HE HAD ANOTHER SAE  
(AE#4), BILATERAL  
PNEUMOTHORAX WHEN HIS  
CHEST TUBES WERE REMOVED,  
WHICH PROLONGED HIS  
HOSPITAL STAY TO 23MAR21.

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

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID	USA-US074-2021-MRNA-1273-P30 1000020
Adverse event	BILATERAL PNEUMOTHORAX
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

377 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

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

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

---

SUBJECT UNDERWENT 5  
VESSEL CORONARY BYPASS  
ON 12MAR21. WHEN CHEST  
TUBES WERE REMOVED ON  
16MAR21, LEFT LUNG  
COLLAPSED AND RIGHT LUNG  
PARTIALLY COLLAPSED.  
SMALL CHEST TUBES WERE  
INSERTED TO EVACUATE THE  
AIR, AND THIS PROLONGED  
HOSPITAL STAY.

---

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

---

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID	
Adverse event	CORONARY ARTERY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 MAR 2021
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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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) _____	

US3162072

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID

Adverse event

SUBCUTANEOUS EMPHYSEMA  
UPPER THORAX

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)

17 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

382 of 2865

EAB) (1725)

US3162072

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

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

US3162072

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

AEID	
Adverse event	ACUTE LACUNAR INFARCT, LEFT HEMISPHERE
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)	20 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 23:00:12

Generated On: 09 Jun 2021 15:29:54

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

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 01:02:58

Generated On: 09 Jun 2021 15:29:54

---

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

Yes ☒

No ☐

---

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

---

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 2000	
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"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 2000	
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"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 2000
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"/>	

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 2000
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"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE VIRAL INFECTION,  
UNSPECIFIED

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

397 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	8 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication FLUZONE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

399 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENT CORONARY  
THROMBOSIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

401 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)		23 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

403 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

405 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐

PRODUCTION RELEASE (v12.003

407 of 2865

EAB) (1725)

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

409 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication COLCHICINE

Prophylaxis Yes ☐  
No ☒

Indication SUBCUTANEOUS EMPHYSEMA  
UPPER THORAX

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

411 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication CRESCENDO ANGINA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

413 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS MYOCARDIAL  
INFARCTION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

415 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication SODIUM CHLORIDE FLUSH FOR  
SALINE LOCK

Prophylaxis Yes ☐  
No ☒

Indication PROPHYLAXIS AGAINST LINE  
CLOTTING OFF

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

417 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

419 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☒  
No ☐

Indication PREVENT PAIN FROM RIGHT  
RADIAL ARTERIAL LINE  
PLACEMENT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

421 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENT CLOT DURING  
ANGIOGRAPHY

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

423 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENT SPASM OF  
CORONARY ARTERIES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

425 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication VERAPAMIL

Prophylaxis Yes ☒  
No ☐

Indication PREVENT SPASM OF  
CORONARY ARTERIES

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

427 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication CONSCIOUS SEDATION FOR ANGIOGRAPHY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

429 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication CONSCIOUS SEDATION FOR  
ANGIOGRAPHY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

431 of 2865

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 23:00:13

Generated On: 09 Jun 2021 15:29:54

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:29:33

Generated On: 09 Jun 2021 15:29:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Apr 2021 23:00:15

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 MAR 2021	5 VESSEL CORONARY BYPASS SURGERY	Adverse Event	
11 MAR 2021	EKG ( EMERGENCY ROOM)	Adverse Event	
11 MAR 2021	EKG (EMERGENCY ROOM)	Adverse Event	
11 MAR 2021	STRESS ECHO	Adverse Event	
16 MAR 2021	BILATERAL CHEST TUBE INSERTION	Adverse Event	
11 MAR 2021	CHEST X-RAY	Adverse Event	
11 MAR 2021	ECG (DIFFERENT HOSPITAL)	Adverse Event	
12 MAR 2021	ECG	Adverse Event	
13 MAR 2021	ECG	Adverse Event	
12 MAR 2021	PLACEMENT OF ARTERIAL LINE	Other	PRE-OPERATIVE PROCEDURE
12 MAR 2021	PLACEMENT OF CENTRAL LINE	Other	PRE-OPERATIVE PROCEDURE
12 MAR 2021	SPIROMETRY	Other	PRE-OPERATIVE PROCEDURE
12 MAR 2021	TRANS-ESOPHAGEAL ECHO	Other	INTRA-OPERATIVE PROCEDURE
14 MAR 2021	TRANS-THORACIC ECHO	Other	POST-OPERATIVE MONITORING
11 MAR 2021	CHEST-X-RAY (DIFFERENT HOSPITAL)	Diagnostic	
12 MAR 2021	CHEST X-RAY	Diagnostic	
13 MAR 2021	CHEST X-RAY	Diagnostic	
14 MAR 2021	CHEST X-RAY	Diagnostic	
15 MAR 2021	CHEST X-RAY	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

434 of 2865

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Data signed: (b) (4) 24 Apr 2021 23:00:15

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 MAR 2021	CHEST X-RAY (3)	Adverse Event	
17 MAR 2021	CHEST X-RAY	Adverse Event	
18 MAR 2021	CHEST X-RAY	Adverse Event	
19 MAR 2021	CHEST X-RAY	Adverse Event	
20 MAR 2021	CHEST X-RAY	Adverse Event	
21 MAR 2021	CHEST X-RAY	Adverse Event	
22 MAR 2021	CHEST X-RAY (2)	Adverse Event	
23 MAR 2021	CHEST X-RAY	Adverse Event	
20 MAR 2021	BRAIN MRI	Adverse Event	
11 MAR 2021	CORONARY ANGIOGRAPHY	Adverse Event	
11 MAR 2021	PLACEMENT OF ARTERIAL LINE FOR ANGIOGRAPHY	Diagnostic	
12 MAR 2021	PLACEMENT OF FOLEY CATHETER	Other	PRE-OPERATIVE PROCEDURE
12 MAR 2021	RIGHT LOWER EXTREMITY ENDOSCOPIC VEIN HARVEST	Adverse Event	
12 MAR 2021	ENDOTRACHEAL INTUBATION	Other	PRE-OPERATIVE PROCEDURE FOR ANESTHESIA

US3162072

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:29:54

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 ☐

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

SAEID	USA-US074-2021-MRNA-1273-P301000020
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)	3

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

SAEID	USA-US074-2021-MRNA-1273-P301000020
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)	3
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

SAEID	USA-US074-2021-MRNA-1273-P301000020
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)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 10:05
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

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 23:00:16

Generated On: 09 Jun 2021 15:29:54

SAEID	USA-US074-2021-MRNA-1273-P301000020
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)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 09:01
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

US3162072 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

**US3162072**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:29:54**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 16:41:07
User entered 'US3162072'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:22

**US3162072**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 16:54:03
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:42

US3162072

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 16:54:03
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:23

US3162072

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 16:54:03
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:42

**US3162072**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'SCRN'	System	07 Aug 2020 04:40:42

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:24

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '71'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

**US3162072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:54**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'YEARS'	System	07 Aug 2020 04:40:54

**US3162072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:54**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '71'	System	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered 'Male (M)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

**US3162072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:54**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

**US3162072**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:54**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:29:49
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:40:54

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

**US3162072**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Aug 2020'	System	06 Aug 2020 22:55:04

**US3162072**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '2020'	System	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
Query 'The date of the ICF corresponds to Protocol Amendment 2, please verify, 'Thank you,' canceled (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 18:34:21
User opened query 'The date of the ICF corresponds to Protocol Amendment 2, please verify, 'Thank you,' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 18:33:02
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

**US3162072**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:54**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:04

US3162072

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:33
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:23

**US3162072**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:54**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'I'	System	06 Aug 2020 22:55:17

US3162072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:37:43
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:55:17

US3162072

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:29:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 16:57:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:01

US3162072

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:43:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:43:07
Data point term sent to Coder	System	07 Aug 2020 04:41:53
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

US3162072

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'un UNK 2004'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

US3162072

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

US3162072

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Jan 2004'	System	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '2004'	System	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	07 Aug 2020 04:41:16

**US3162072**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	07 Aug 2020 04:41:16

US3162072

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:43:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:43:06
Data point term sent to Coder	System	07 Aug 2020 04:41:52
User entered 'seasonal allergies'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

US3162072

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'un UNK 1979'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

US3162072

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Jan 1979'	System	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '1979'	System	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	07 Aug 2020 04:41:27

**US3162072**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	07 Aug 2020 04:41:27

US3162072

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:07
Data point term sent to Coder	System	14 Aug 2020 23:59:24
Datapoint queued for coding (5024686).	System	14 Aug 2020 23:59:12
Data point term sent to Coder	System	07 Aug 2020 04:41:52
User entered 'deviated septum'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

US3162072

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'un UNK 1983'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

US3162072

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

**US3162072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

US3162072

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered 'un Dec 2019'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

US3162072

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:00
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:41:48

**US3162072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Jan 1983'	System	07 Aug 2020 04:41:48

**US3162072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '1983'	System	07 Aug 2020 04:41:48

**US3162072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Dec 2019'	System	07 Aug 2020 04:41:48

**US3162072**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '2019'	System	07 Aug 2020 04:41:48

US3162072

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 23:39:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 23:39:05
Data point term sent to Coder	System	15 Apr 2021 23:37:40
User entered 'Hyperlipdemia'	(b) (4), (b) (6)	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User entered 'UN UNK 2015'	(b) (4), (b) (6)	15 Apr 2021 23:36:51

US3162072

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:36:51

US3162072

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'Jan 2015'	System	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '2015'	System	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	15 Apr 2021 23:36:51

**US3162072**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered empty.	System	15 Apr 2021 23:36:51

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered '14:32'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered '6 Aug 2020 14:32'	System	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered '71' in	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35
DataPoint set to visible.	System	06 Aug 2020 22:55:17

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered '180' lb	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35
DataPoint set to visible.	System	06 Aug 2020 22:55:17

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
Amendment Manager: User entered '25.15740'	System	16 Sep 2020 23:46:38
User entered '25.2'	System	07 Aug 2020 04:42:35
DataPoint set to visible.	System	06 Aug 2020 22:55:17

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'kg/m2'	System	07 Aug 2020 04:42:35
DataPoint set to visible.	System	06 Aug 2020 22:55:17

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
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)	14 Sep 2020 17:48:34
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) (b) (4)	11 Sep 2020 02:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
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 17:13:29
User entered '97.6' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered empty; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
User entered '70'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'bpm'	System	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'breaths/min'	System	07 Aug 2020 04:42:35

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
User entered '123'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'mmHg'	System	07 Aug 2020 04:42:35

US3162072

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	11 Sep 2020 02:06:14
User entered '76'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User entered 'mmHg'	System	07 Aug 2020 04:42:35

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49

**US3162072**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49

US3162072

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:49:06
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:43

US3162072

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:49:06
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).		04 Sep 2020 03:30:14
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:42:43

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

**US3162072**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:29:54**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

**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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

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)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

US3162072

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:49:58
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:02

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:50:12
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:12

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:50:12
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:12

US3162072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:50:12
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:12

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'VISIT1'	System	07 Aug 2020 04:43:12

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:04:25

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:44:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:44:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 22:04:25
User entered '185048' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:04:25

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:04:25

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:54**

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:22

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:54**

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:22

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:22

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:54**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:22

US3162072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:50:39
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:43:22

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:29:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '14:32'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '6 Aug 2020 14:32'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '97.6' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '70'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'bpm'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'breaths/min'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '123'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '76'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:29:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User closed query 'Source documents note the time as 16:25, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 18:07:28
Query 'Source documents note the time as 16:25, please verify. Thank you.' answered with 'Verified against source documents. Time of assessment is 16:22' (Site from CRA).	Jourdan Manfred (b) (4) (b) (4)	14 Sep 2020 20:18:07
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User opened query 'Source documents note the time as 16:25, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 18:45:50
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)	18 Aug 2020 18:18:11
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).		07 Aug 2020 04:44:48
User entered '16:22'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '6 Aug 2020 16:22'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '97.3' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '62'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'bpm'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'breaths/min'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '128'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:34
User entered '81'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:48

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	07 Aug 2020 04:44:48

US3162072

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:49
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:53

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:46:49
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:44:53

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered '15:47'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '6 Aug 2020 15:47'	System	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:52:19
User entered 'ONCE'	System	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 22:56:56

US3162072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:53:26
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:06

US3162072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:53:26
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:06

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:53:26
User entered '15:35'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:06

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '6 Aug 2020 15:35'	System	07 Aug 2020 04:45:06

US3162072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:03
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

US3162072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:03
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:03
User entered '15:40'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '6 Aug 2020 15:40'	System	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	07 Aug 2020 04:45:15

US3162072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:03
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:03
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:15

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered empty.	System	07 Aug 2020 04:45:15

US3162072

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 18:54:13
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:24

**US3162072**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	07 Aug 2020 04:45:24

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:18:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '39cabf66-2a12-4b17-9060-e2c6386c0e72'	System	06 Aug 2020 23:19:31
User entered 'Yes (Y)'	System	06 Aug 2020 23:19:31

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:19:08', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '39cabf66-2a12-4b17-9060-e2c6386c0e72'	System	06 Aug 2020 23:19:31
User entered '97.3'	System	06 Aug 2020 23:19:31

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:19:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '39cabf66-2a12-4b17-9060-e2c6386c0e72'	System	06 Aug 2020 23:19:31
User entered 'No (N)'	System	06 Aug 2020 23:19:31

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:19:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '39cabf66-2a12-4b17-9060-e2c6386c0e72'	System	06 Aug 2020 23:19:31
User entered '06 Aug 2020 16:19'	System	06 Aug 2020 23:19:31

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 16:07'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 18:37'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:33:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2cdb992-d4c7-462e-b5f8-821a6b86f9b1'	System	07 Aug 2020 03:34:20
User entered 'Yes (Y)'	System	07 Aug 2020 03:34:20

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:04', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2cdbc992-d4c7-462e-b5f8-821a6b86f9b1'	System	07 Aug 2020 03:34:20
User entered '96.7'	System	07 Aug 2020 03:34:20

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2cdb992-d4c7-462e-b5f8-821a6b86f9b1'	System	07 Aug 2020 03:34:20
User entered 'No (N)'	System	07 Aug 2020 03:34:20

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:17', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2cdbc992-d4c7-462e-b5f8-821a6b86f9b1'	System	07 Aug 2020 03:34:20
User entered '06 Aug 2020 20:34'	System	07 Aug 2020 03:34:20

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 19:32'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 2'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6bbcca35-fc8b-436d-bc73-475c8ee7406a'	System	08 Aug 2020 03:05:42
User entered 'Yes (Y)'	System	08 Aug 2020 03:05:42

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:26', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6bbcca35-fc8b-436d-bc73-475c8ee7406a'	System	08 Aug 2020 03:05:42
User entered '98.0'	System	08 Aug 2020 03:05:42

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:32', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6bbcca35-fc8b-436d-bc73-475c8ee7406a'	System	08 Aug 2020 03:05:42
User entered 'No (N)'	System	08 Aug 2020 03:05:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6bbcca35-fc8b-436d-bc73-475c8ee7406a'	System	08 Aug 2020 03:05:42
User entered '07 Aug 2020 20:05'	System	08 Aug 2020 03:05:42

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 3'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2d71ae60-eb14-420a-8eb7-747c72e28698'	System	09 Aug 2020 02:50:40
User entered 'Yes (Y)'	System	09 Aug 2020 02:50:40

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:23', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2d71ae60-eb14-420a-8eb7-747c72e28698'	System	09 Aug 2020 02:50:40
User entered '98.0'	System	09 Aug 2020 02:50:40

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2d71ae60-eb14-420a-8eb7-747c72e28698'	System	09 Aug 2020 02:50:40
User entered 'No (N)'	System	09 Aug 2020 02:50:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2d71ae60-eb14-420a-8eb7-747c72e28698'	System	09 Aug 2020 02:50:40
User entered '08 Aug 2020 19:50'	System	09 Aug 2020 02:50:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 4'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3a1fcd6a-32c1-436f-9a0e-dc4dd8128154'	System	10 Aug 2020 03:56:27
User entered 'Yes (Y)'	System	10 Aug 2020 03:56:27

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:12', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3a1fcd6a-32c1-436f-9a0e-dc4dd8128154'	System	10 Aug 2020 03:56:27
User entered '97.4'	System	10 Aug 2020 03:56:27

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:16', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3a1fcd6a-32c1-436f-9a0e-dc4dd8128154'	System	10 Aug 2020 03:56:27
User entered 'No (N)'	System	10 Aug 2020 03:56:27

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3a1fcd6a-32c1-436f-9a0e-dc4dd8128154'	System	10 Aug 2020 03:56:27
User entered '09 Aug 2020 20:56'	System	10 Aug 2020 03:56:27

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 5'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:50:47', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b312139a-bcad-440f-8955-03e1a915838b'	System	11 Aug 2020 03:50:56
User entered 'Yes (Y)'	System	11 Aug 2020 03:50:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:50:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b312139a-bcad-440f-8955-03e1a915838b' User entered '97.4'	System	11 Aug 2020 03:50:56
	System	11 Aug 2020 03:50:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:50:43', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b312139a-bcad-440f-8955-03e1a915838b'	System	11 Aug 2020 03:50:56
User entered 'No (N)'	System	11 Aug 2020 03:50:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:50:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b312139a-bcad-440f-8955-03e1a915838b'	System	11 Aug 2020 03:50:56
User entered '10 Aug 2020 20:50'	System	11 Aug 2020 03:50:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 6'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07154ea9-417e-4273-9494-016bb69a0c35'	System	12 Aug 2020 03:30:48
User entered 'Yes (Y)'	System	12 Aug 2020 03:30:48

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:20', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07154ea9-417e-4273-9494-016bb69a0c35'	System	12 Aug 2020 03:30:48
User entered '97.3'	System	12 Aug 2020 03:30:48

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07154ea9-417e-4273-9494-016bb69a0c35'	System	12 Aug 2020 03:30:48
User entered 'No (N)'	System	12 Aug 2020 03:30:48

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07154ea9-417e-4273-9494-016bb69a0c35'	System	12 Aug 2020 03:30:48
User entered '11 Aug 2020 20:30'	System	12 Aug 2020 03:30:48

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 7'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:38:59', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '1790f23d-0da8-4095-a1cf-dbc98eb7387f'	System	13 Aug 2020 03:39:21
User entered 'Yes (Y)'	System	13 Aug 2020 03:39:21

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '1790f23d-0da8-4095-a1cf-dbc98eb7387f' User entered '97.9'	System	13 Aug 2020 03:39:21
	System	13 Aug 2020 03:39:21

US3162072

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '1790f23d-0da8-4095-a1cf-dbc98eb7387f'	System	13 Aug 2020 03:39:21
User entered 'No (N)'	System	13 Aug 2020 03:39:21

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:17', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '1790f23d-0da8-4095-a1cf-dbc98eb7387f'	System	13 Aug 2020 03:39:21
User entered '12 Aug 2020 20:39'	System	13 Aug 2020 03:39:21

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:19:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9c599567-421a-4d4b-bfd4-f6d8041bd6ac'	System	06 Aug 2020 23:20:46
User entered 'None (1)'	System	06 Aug 2020 23:20:46

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:20:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9c599567-421a-4d4b-bfd4-f6d8041bd6ac'	System	06 Aug 2020 23:20:46
User entered 'No (N)'	System	06 Aug 2020 23:20:46

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:20:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9c599567-421a-4d4b-bfd4-f6d8041bd6ac'	System	06 Aug 2020 23:20:46
User entered 'No (N)'	System	06 Aug 2020 23:20:46

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:20:37', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9c599567-421a-4d4b-bfd4-f6d8041bd6ac'	System	06 Aug 2020 23:20:46
User entered 'None (1)'	System	06 Aug 2020 23:20:46

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:20:43', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9c599567-421a-4d4b-bfd4-f6d8041bd6ac'	System	06 Aug 2020 23:20:46
User entered '06 Aug 2020 16:20'	System	06 Aug 2020 23:20:46

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 16:07'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 18:37'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '63e2cb21-0ff4-40da-b1b6-d176ceb22c0b'	System	07 Aug 2020 03:34:53
User entered 'None (1)'	System	07 Aug 2020 03:34:53

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '63e2cb21-0ff4-40da-b1b6-d176ceb22c0b'	System	07 Aug 2020 03:34:53
User entered 'No (N)'	System	07 Aug 2020 03:34:53

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '63e2cb21-0ff4-40da-b1b6-d176ceb22c0b'	System	07 Aug 2020 03:34:53
User entered 'No (N)'	System	07 Aug 2020 03:34:53

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '63e2cb21-0ff4-40da-b1b6-d176ceb22c0b'	System	07 Aug 2020 03:34:53
User entered 'None (1)'	System	07 Aug 2020 03:34:53

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:51', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '63e2cb21-0ff4-40da-b1b6-d176ceb22c0b'	System	07 Aug 2020 03:34:53
User entered '06 Aug 2020 20:34'	System	07 Aug 2020 03:34:53

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 19:32'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 2'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:47', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'bf91ed3d-c656-4613-bf20-fb818704b9fd'	System	08 Aug 2020 03:06:10
User entered 'None (1)'	System	08 Aug 2020 03:06:10

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'bf91ed3d-c656-4613-bf20-fb818704b9fd'	System	08 Aug 2020 03:06:10
User entered 'No (N)'	System	08 Aug 2020 03:06:10

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:05:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'bf91ed3d-c656-4613-bf20-fb818704b9fd'	System	08 Aug 2020 03:06:10
User entered 'No (N)'	System	08 Aug 2020 03:06:10

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'bf91ed3d-c656-4613-bf20-fb818704b9fd'	System	08 Aug 2020 03:06:10
User entered 'None (1)'	System	08 Aug 2020 03:06:10

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'bf91ed3d-c656-4613-bf20-fb818704b9fd'	System	08 Aug 2020 03:06:10
User entered '07 Aug 2020 20:06'	System	08 Aug 2020 03:06:10

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 3'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7cd2b534-a1aa-4109-a629-2f3c6ee2850f'	System	09 Aug 2020 02:51:11
User entered 'None (1)'	System	09 Aug 2020 02:51:11

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7cd2b534-a1aa-4109-a629-2f3c6ee2850f'	System	09 Aug 2020 02:51:11
User entered 'No (N)'	System	09 Aug 2020 02:51:11

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:50:51', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7cd2b534-a1aa-4109-a629-2f3c6ee2850f'	System	09 Aug 2020 02:51:11
User entered 'No (N)'	System	09 Aug 2020 02:51:11

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7cd2b534-a1aa-4109-a629-2f3c6ee2850f'	System	09 Aug 2020 02:51:11
User entered 'None (1)'	System	09 Aug 2020 02:51:11

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7cd2b534-a1aa-4109-a629-2f3c6ee2850f'	System	09 Aug 2020 02:51:11
User entered '08 Aug 2020 19:51'	System	09 Aug 2020 02:51:11

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 4'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff755a7e-bcdc-409d-ab1a-95ebde0964f1'	System	10 Aug 2020 03:57:04
User entered 'None (1)'	System	10 Aug 2020 03:57:04

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff755a7e-bcdc-409d-ab1a-95ebde0964f1'	System	10 Aug 2020 03:57:04
User entered 'No (N)'	System	10 Aug 2020 03:57:04

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff755a7e-bcdc-409d-ab1a-95ebde0964f1'	System	10 Aug 2020 03:57:04
User entered 'No (N)'	System	10 Aug 2020 03:57:04

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:56:57', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff755a7e-bcdc-409d-ab1a-95ebde0964f1'	System	10 Aug 2020 03:57:04
User entered 'None (1)'	System	10 Aug 2020 03:57:04

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:01', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff755a7e-bcdc-409d-ab1a-95ebde0964f1'	System	10 Aug 2020 03:57:04
User entered '09 Aug 2020 20:57'	System	10 Aug 2020 03:57:04

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 5'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '850733f7-4993-4adc-bee2-4c3872c93003'	System	11 Aug 2020 03:51:24
User entered 'None (1)'	System	11 Aug 2020 03:51:24

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '850733f7-4993-4adc-bee2-4c3872c93003'	System	11 Aug 2020 03:51:24
User entered 'No (N)'	System	11 Aug 2020 03:51:24

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:08', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '850733f7-4993-4adc-bee2-4c3872c93003'	System	11 Aug 2020 03:51:24
User entered 'No (N)'	System	11 Aug 2020 03:51:24

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '850733f7-4993-4adc-bee2-4c3872c93003'	System	11 Aug 2020 03:51:24
User entered 'None (1)'	System	11 Aug 2020 03:51:24

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '850733f7-4993-4adc-bee2-4c3872c93003'	System	11 Aug 2020 03:51:24
User entered '10 Aug 2020 20:51'	System	11 Aug 2020 03:51:24

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 6'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5b0901e0-d47d-4cf4-bc57-b71095ecae0c'	System	12 Aug 2020 03:31:12
User entered 'None (1)'	System	12 Aug 2020 03:31:12

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:56', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5b0901e0-d47d-4cf4-bc57-b71095ecae0c'	System	12 Aug 2020 03:31:12
User entered 'No (N)'	System	12 Aug 2020 03:31:12

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:30:59', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5b0901e0-d47d-4cf4-bc57-b71095ecae0c'	System	12 Aug 2020 03:31:12
User entered 'No (N)'	System	12 Aug 2020 03:31:12

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:06', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5b0901e0-d47d-4cf4-bc57-b71095ecae0c'	System	12 Aug 2020 03:31:12
User entered 'None (1)'	System	12 Aug 2020 03:31:12

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5b0901e0-d47d-4cf4-bc57-b71095ecae0c'	System	12 Aug 2020 03:31:12
User entered '11 Aug 2020 20:31'	System	12 Aug 2020 03:31:12

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 7'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '37481c97-1eba-4000-928d-6bc4f2696c66'	System	13 Aug 2020 03:39:39
User entered 'None (1)'	System	13 Aug 2020 03:39:39

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:26', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '37481c97-1eba-4000-928d-6bc4f2696c66'	System	13 Aug 2020 03:39:39
User entered 'No (N)'	System	13 Aug 2020 03:39:39

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '37481c97-1eba-4000-928d-6bc4f2696c66'	System	13 Aug 2020 03:39:39
User entered 'No (N)'	System	13 Aug 2020 03:39:39

US3162072

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '37481c97-1eba-4000-928d-6bc4f2696c66'	System	13 Aug 2020 03:39:39
User entered 'None (1)'	System	13 Aug 2020 03:39:39

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '37481c97-1eba-4000-928d-6bc4f2696c66'	System	13 Aug 2020 03:39:39
User entered '12 Aug 2020 20:39'	System	13 Aug 2020 03:39:39

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:07', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:17', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'None (0)'	System	06 Aug 2020 23:21:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:26', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered 'No (N)'	System	06 Aug 2020 23:21:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T16:21:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '413bf463-0e1c-4019-8e95-b1440d198a75'	System	06 Aug 2020 23:21:42
User entered '06 Aug 2020 16:21'	System	06 Aug 2020 23:21:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 16:07'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 18:37'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:34:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:08', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'None (0)'	System	07 Aug 2020 03:35:25

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered 'No (N)'	System	07 Aug 2020 03:35:25

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-06T20:35:23', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '422cbc78-5cb8-46bb-88ae-1011edc12834'	System	07 Aug 2020 03:35:25
User entered '06 Aug 2020 20:35'	System	07 Aug 2020 03:35:25

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Aug 2020 19:32'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 2'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'None (0)'	System	08 Aug 2020 03:06:42

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered 'No (N)'	System	08 Aug 2020 03:06:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-07T20:06:41', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '179be250-8b65-4032-b68a-5a2f0fdcc509'	System	08 Aug 2020 03:06:42
User entered '07 Aug 2020 20:06'	System	08 Aug 2020 03:06:42

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 3'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:17', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'None (0)'	System	09 Aug 2020 02:51:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:35', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered 'No (N)'	System	09 Aug 2020 02:51:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-08T19:51:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9af48aeb-217c-496b-ab55-806822b47d55'	System	09 Aug 2020 02:51:40
User entered '08 Aug 2020 19:51'	System	09 Aug 2020 02:51:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 4'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:07', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:16', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:19', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'None (0)'	System	10 Aug 2020 03:57:28

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered 'No (N)'	System	10 Aug 2020 03:57:28

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-09T20:57:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd2c5320d-da3a-4e54-b3f1-92d6b0205327'	System	10 Aug 2020 03:57:28
User entered '09 Aug 2020 20:57'	System	10 Aug 2020 03:57:28

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 5'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:31', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:41', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'None (0)'	System	11 Aug 2020 03:51:51

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered 'No (N)'	System	11 Aug 2020 03:51:51

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-10T20:51:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '74d6f99f-2f5c-41fa-ae30-3d64ebc6f74e'	System	11 Aug 2020 03:51:51
User entered '10 Aug 2020 20:51'	System	11 Aug 2020 03:51:51

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 6'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:19', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:25', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'None (0)'	System	12 Aug 2020 03:31:40

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered 'No (N)'	System	12 Aug 2020 03:31:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-11T20:31:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5a9dbf3d-c98f-4a06-8679-749774d9f012'	System	12 Aug 2020 03:31:40
User entered '11 Aug 2020 20:31'	System	12 Aug 2020 03:31:40

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 7'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:55', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'None (0)'	System	13 Aug 2020 03:40:07

US3162072

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:39:59', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered 'No (N)'	System	13 Aug 2020 03:40:07

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-08-12T20:40:04', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5cc10586-982c-4f5a-bd45-f0c5318a64af'	System	13 Aug 2020 03:40:07
User entered '12 Aug 2020 20:40'	System	13 Aug 2020 03:40:07

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:56:56

**US3162072**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:56:56

US3162072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:47:42
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:47:09

**US3162072**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:47:42
User entered '13 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:47:09

**US3162072**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:47:42
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:47:09

US3162072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:47:42
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:47:09

US3162072

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:47:50
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:47:18

**US3162072**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	14 Aug 2020 04:47:18

**US3162072**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:03
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:20:16

**US3162072**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:03
User entered '20 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:20:16

**US3162072**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:03
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:20:16

US3162072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:03
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:20:16

US3162072

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:20:20

**US3162072**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	21 Aug 2020 05:20:20

**US3162072**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:24:02

**US3162072**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:20
User entered '27 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:24:02

US3162072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:20
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:24:02

US3162072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:20
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:24:02

US3162072

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 22:48:25
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:24:07

**US3162072**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	31 Aug 2020 17:24:07

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:29:57
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:30:14

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:29:57
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:30:14

US3162072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:29:57
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:30:14

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'VISIT2'	System	04 Sep 2020 03:30:14

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '14:15'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '3 Sep 2020 14:15'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '99.1' F	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '65'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'bpm'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'breaths/min'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '120'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '76'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '15:22'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '3 Sep 2020 15:22'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '97.8' F	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '67'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'bpm'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'breaths/min'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '120'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:30:42
User entered '79'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:21

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	04 Sep 2020 03:31:21

US3162072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Jan 2021 01:26:43
User closed query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Jan 2021 01:26:39
Query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' answered with 'updated per query' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	19 Jan 2021 06:39:39
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	19 Jan 2021 06:39:22
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	19 Jan 2021 06:38:58
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	19 Jan 2021 06:38:58
User opened query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 23:31:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:26

US3162072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	23 Jan 2021 01:26:43
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	19 Jan 2021 06:39:22
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:26

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered '3 Sep 2020'	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered '14:46'	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '3 Sep 2020 14:46'	System	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered 'Left Arm (LEFT ARM)'	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:00
User entered 'ONCE'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 21:50:07

US3162072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:38

US3162072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:38
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:38

US3162072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:32:38
User entered '14:33'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:38

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '3 Sep 2020 14:33'	System	04 Sep 2020 03:31:38

US3162072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:11
User entered '3 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:11
User entered '14:36'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '3 Sep 2020 14:36'	System	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	04 Sep 2020 03:31:52

US3162072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:11
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:11
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:52

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered empty.	System	04 Sep 2020 03:31:52

US3162072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:33:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	04 Sep 2020 03:31:56

**US3162072**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	04 Sep 2020 03:31:56

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:21:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ce28af52-1144-4542-985f-472b52412563'	System	03 Sep 2020 22:21:49
User entered 'Yes (Y)'	System	03 Sep 2020 22:21:49

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:21:35', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ce28af52-1144-4542-985f-472b52412563'	System	03 Sep 2020 22:21:49
User entered '97.8'	System	03 Sep 2020 22:21:49

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:21:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ce28af52-1144-4542-985f-472b52412563'	System	03 Sep 2020 22:21:49
User entered 'No (N)'	System	03 Sep 2020 22:21:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:21:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ce28af52-1144-4542-985f-472b52412563'	System	03 Sep 2020 22:21:49
User entered '03 Sep 2020 15:21'	System	03 Sep 2020 22:21:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 15:06'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 17:36'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:25:59', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2382b594-7bd3-4297-bec4-b0aa777c8b77'	System	04 Sep 2020 03:26:06
User entered 'Yes (Y)'	System	04 Sep 2020 03:26:06

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:25:37', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2382b594-7bd3-4297-bec4-b0aa777c8b77'	System	04 Sep 2020 03:26:06
User entered '97.8'	System	04 Sep 2020 03:26:06

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:25:54', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2382b594-7bd3-4297-bec4-b0aa777c8b77'	System	04 Sep 2020 03:26:06
User entered 'No (N)'	System	04 Sep 2020 03:26:06

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2382b594-7bd3-4297-bec4-b0aa777c8b77'	System	04 Sep 2020 03:26:06
User entered '03 Sep 2020 20:26'	System	04 Sep 2020 03:26:06

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 18:31'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 2'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:04', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c4fd4d11-05be-4c26-bfec-c83899585150'	System	05 Sep 2020 02:27:17
User entered 'Yes (Y)'	System	05 Sep 2020 02:27:17

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:26:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c4fd4d11-05be-4c26-bfec-c83899585150'	System	05 Sep 2020 02:27:17
User entered '98.4'	System	05 Sep 2020 02:27:17

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:26:59', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c4fd4d11-05be-4c26-bfec-c83899585150'	System	05 Sep 2020 02:27:17
User entered 'No (N)'	System	05 Sep 2020 02:27:17

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c4fd4d11-05be-4c26-bfec-c83899585150'	System	05 Sep 2020 02:27:17
User entered '04 Sep 2020 19:27'	System	05 Sep 2020 02:27:17

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 3'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:29:52', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af3e5df4-32e0-465a-9227-6b54f7cb5495'	System	06 Sep 2020 02:29:58
User entered 'Yes (Y)'	System	06 Sep 2020 02:29:58

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:29:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af3e5df4-32e0-465a-9227-6b54f7cb5495'	System	06 Sep 2020 02:29:58
User entered '98.6'	System	06 Sep 2020 02:29:58

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:29:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af3e5df4-32e0-465a-9227-6b54f7cb5495'	System	06 Sep 2020 02:29:58
User entered 'No (N)'	System	06 Sep 2020 02:29:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:29:57', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af3e5df4-32e0-465a-9227-6b54f7cb5495'	System	06 Sep 2020 02:29:58
User entered '05 Sep 2020 19:29'	System	06 Sep 2020 02:29:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 4'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9dd3bfa6-4b76-43e1-a77c-134c305d7ed9'	System	07 Sep 2020 03:52:30
User entered 'Yes (Y)'	System	07 Sep 2020 03:52:30

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9dd3bfa6-4b76-43e1-a77c-134c305d7ed9' User entered '97.4'	System	07 Sep 2020 03:52:30
	System	07 Sep 2020 03:52:30

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9dd3bfa6-4b76-43e1-a77c-134c305d7ed9'	System	07 Sep 2020 03:52:30
User entered 'No (N)'	System	07 Sep 2020 03:52:30

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '9dd3bfa6-4b76-43e1-a77c-134c305d7ed9'	System	07 Sep 2020 03:52:30
User entered '06 Sep 2020 20:52'	System	07 Sep 2020 03:52:30

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 5'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:34:51', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6b02c527-912c-4392-be54-fd4a3989b12b'	System	08 Sep 2020 02:34:58
User entered 'Yes (Y)'	System	08 Sep 2020 02:34:58

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:34:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6b02c527-912c-4392-be54-fd4a3989b12b' User entered '98.1'	System	08 Sep 2020 02:34:58
	System	08 Sep 2020 02:34:58

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:34:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6b02c527-912c-4392-be54-fd4a3989b12b'	System	08 Sep 2020 02:34:58
User entered 'No (N)'	System	08 Sep 2020 02:34:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:34:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '6b02c527-912c-4392-be54-fd4a3989b12b'	System	08 Sep 2020 02:34:58
User entered '07 Sep 2020 19:34'	System	08 Sep 2020 02:34:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 6'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:46:08', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'de648adb-e10f-4ef6-8575-7a9b53f26390'	System	09 Sep 2020 04:46:56
User entered 'Yes (Y)'	System	09 Sep 2020 04:46:56

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:46:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'de648adb-e10f-4ef6-8575-7a9b53f26390'	System	09 Sep 2020 04:46:56
User entered '97.3'	System	09 Sep 2020 04:46:56

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:46:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'de648adb-e10f-4ef6-8575-7a9b53f26390'	System	09 Sep 2020 04:46:56
User entered 'No (N)'	System	09 Sep 2020 04:46:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:46:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'de648adb-e10f-4ef6-8575-7a9b53f26390'	System	09 Sep 2020 04:46:56
User entered '08 Sep 2020 21:46'	System	09 Sep 2020 04:46:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 7'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:09:55', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a03e460f-175b-42ae-a15f-d4381690cd8f'	System	10 Sep 2020 03:10:03
User entered 'Yes (Y)'	System	10 Sep 2020 03:10:03

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:09:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a03e460f-175b-42ae-a15f-d4381690cd8f' User entered '97.3'	System	10 Sep 2020 03:10:03
	System	10 Sep 2020 03:10:03

US3162072

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:09:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a03e460f-175b-42ae-a15f-d4381690cd8f'	System	10 Sep 2020 03:10:03
User entered 'No (N)'	System	10 Sep 2020 03:10:03

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a03e460f-175b-42ae-a15f-d4381690cd8f'	System	10 Sep 2020 03:10:03
User entered '09 Sep 2020 20:10'	System	10 Sep 2020 03:10:03

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:18:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7f5ed9bd-1220-4f3d-b46e-873f5ec7c8b9'	System	03 Sep 2020 22:18:40
User entered 'None (1)'	System	03 Sep 2020 22:18:40

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:18:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7f5ed9bd-1220-4f3d-b46e-873f5ec7c8b9'	System	03 Sep 2020 22:18:40
User entered 'No (N)'	System	03 Sep 2020 22:18:40

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:18:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7f5ed9bd-1220-4f3d-b46e-873f5ec7c8b9'	System	03 Sep 2020 22:18:40
User entered 'No (N)'	System	03 Sep 2020 22:18:40

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:18:31', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7f5ed9bd-1220-4f3d-b46e-873f5ec7c8b9'	System	03 Sep 2020 22:18:40
User entered 'None (1)'	System	03 Sep 2020 22:18:40

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:18:35', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7f5ed9bd-1220-4f3d-b46e-873f5ec7c8b9'	System	03 Sep 2020 22:18:40
User entered '03 Sep 2020 15:18'	System	03 Sep 2020 22:18:40

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 15:06'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 17:36'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5d29c5fa-bc08-4b22-8855-f8bb75af5d1c'	System	04 Sep 2020 03:26:51
User entered 'None (1)'	System	04 Sep 2020 03:26:51

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5d29c5fa-bc08-4b22-8855-f8bb75af5d1c'	System	04 Sep 2020 03:26:51
User entered 'No (N)'	System	04 Sep 2020 03:26:51

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:28', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5d29c5fa-bc08-4b22-8855-f8bb75af5d1c'	System	04 Sep 2020 03:26:51
User entered 'No (N)'	System	04 Sep 2020 03:26:51

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5d29c5fa-bc08-4b22-8855-f8bb75af5d1c'	System	04 Sep 2020 03:26:51
User entered 'None (1)'	System	04 Sep 2020 03:26:51

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '5d29c5fa-bc08-4b22-8855-f8bb75af5d1c'	System	04 Sep 2020 03:26:51
User entered '03 Sep 2020 20:26'	System	04 Sep 2020 03:26:51

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 18:31'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 2'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:19', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3fd432c7-13e0-4f9c-a7f2-f882afcd326f'	System	05 Sep 2020 02:27:41
User entered 'None (1)'	System	05 Sep 2020 02:27:41

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:23', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3fd432c7-13e0-4f9c-a7f2-f882afcd326f'	System	05 Sep 2020 02:27:41
User entered 'No (N)'	System	05 Sep 2020 02:27:41

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3fd432c7-13e0-4f9c-a7f2-f882afcd326f'	System	05 Sep 2020 02:27:41
User entered 'No (N)'	System	05 Sep 2020 02:27:41

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:35', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3fd432c7-13e0-4f9c-a7f2-f882afcd326f'	System	05 Sep 2020 02:27:41
User entered 'None (1)'	System	05 Sep 2020 02:27:41

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3fd432c7-13e0-4f9c-a7f2-f882afcd326f'	System	05 Sep 2020 02:27:41
User entered '04 Sep 2020 19:27'	System	05 Sep 2020 02:27:41

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 3'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '055772d8-6d07-461a-aa48-4862f91e51cc'	System	06 Sep 2020 02:30:23
User entered 'None (1)'	System	06 Sep 2020 02:30:23

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '055772d8-6d07-461a-aa48-4862f91e51cc'	System	06 Sep 2020 02:30:23
User entered 'No (N)'	System	06 Sep 2020 02:30:23

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '055772d8-6d07-461a-aa48-4862f91e51cc'	System	06 Sep 2020 02:30:23
User entered 'No (N)'	System	06 Sep 2020 02:30:23

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '055772d8-6d07-461a-aa48-4862f91e51cc'	System	06 Sep 2020 02:30:23
User entered 'None (1)'	System	06 Sep 2020 02:30:23

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '055772d8-6d07-461a-aa48-4862f91e51cc'	System	06 Sep 2020 02:30:23
User entered '05 Sep 2020 19:30'	System	06 Sep 2020 02:30:23

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 4'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '40ca3b80-64b4-47d5-97bd-f4b67543ca11'	System	07 Sep 2020 03:52:59
User entered 'None (1)'	System	07 Sep 2020 03:52:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '40ca3b80-64b4-47d5-97bd-f4b67543ca11'	System	07 Sep 2020 03:52:59
User entered 'No (N)'	System	07 Sep 2020 03:52:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '40ca3b80-64b4-47d5-97bd-f4b67543ca11'	System	07 Sep 2020 03:52:59
User entered 'No (N)'	System	07 Sep 2020 03:52:59

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:52', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '40ca3b80-64b4-47d5-97bd-f4b67543ca11'	System	07 Sep 2020 03:52:59
User entered 'None (1)'	System	07 Sep 2020 03:52:59

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:52:56', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '40ca3b80-64b4-47d5-97bd-f4b67543ca11'	System	07 Sep 2020 03:52:59
User entered '06 Sep 2020 20:52'	System	07 Sep 2020 03:52:59

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 5'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2c9dfa0a-9a9c-4c4a-90db-100dcd2691d5'	System	08 Sep 2020 02:35:26
User entered 'None (1)'	System	08 Sep 2020 02:35:26

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:06', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2c9dfa0a-9a9c-4c4a-90db-100dcd2691d5'	System	08 Sep 2020 02:35:26
User entered 'No (N)'	System	08 Sep 2020 02:35:26

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2c9dfa0a-9a9c-4c4a-90db-100dcd2691d5'	System	08 Sep 2020 02:35:26
User entered 'No (N)'	System	08 Sep 2020 02:35:26

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2c9dfa0a-9a9c-4c4a-90db-100dcd2691d5'	System	08 Sep 2020 02:35:26
User entered 'None (1)'	System	08 Sep 2020 02:35:26

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:22', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '2c9dfa0a-9a9c-4c4a-90db-100dcd2691d5'	System	08 Sep 2020 02:35:26
User entered '07 Sep 2020 19:35'	System	08 Sep 2020 02:35:26

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 6'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '82d727d4-8df5-4da1-b8f5-dcd7df594429'	System	09 Sep 2020 04:47:24
User entered 'None (1)'	System	09 Sep 2020 04:47:24

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '82d727d4-8df5-4da1-b8f5-dcd7df594429'	System	09 Sep 2020 04:47:24
User entered 'No (N)'	System	09 Sep 2020 04:47:24

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '82d727d4-8df5-4da1-b8f5-dcd7df594429'	System	09 Sep 2020 04:47:24
User entered 'No (N)'	System	09 Sep 2020 04:47:24

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '82d727d4-8df5-4da1-b8f5-dcd7df594429'	System	09 Sep 2020 04:47:24
User entered 'None (1)'	System	09 Sep 2020 04:47:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '82d727d4-8df5-4da1-b8f5-dcd7df594429'	System	09 Sep 2020 04:47:24
User entered '08 Sep 2020 21:47'	System	09 Sep 2020 04:47:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 7'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:06', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b7ae110b-99a5-48a3-9aa4-9a4c3284b880'	System	10 Sep 2020 03:10:27
User entered 'None (1)'	System	10 Sep 2020 03:10:27

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b7ae110b-99a5-48a3-9aa4-9a4c3284b880'	System	10 Sep 2020 03:10:27
User entered 'No (N)'	System	10 Sep 2020 03:10:27

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b7ae110b-99a5-48a3-9aa4-9a4c3284b880'	System	10 Sep 2020 03:10:27
User entered 'No (N)'	System	10 Sep 2020 03:10:27

US3162072

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b7ae110b-99a5-48a3-9aa4-9a4c3284b880'	System	10 Sep 2020 03:10:27
User entered 'None (1)'	System	10 Sep 2020 03:10:27

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b7ae110b-99a5-48a3-9aa4-9a4c3284b880'	System	10 Sep 2020 03:10:27
User entered '09 Sep 2020 20:10'	System	10 Sep 2020 03:10:27

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'None (0)'	System	03 Sep 2020 22:17:58

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered 'No (N)'	System	03 Sep 2020 22:17:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T15:17:55', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e88ab336-35fd-4d7b-856a-d1bb4e76c352'	System	03 Sep 2020 22:17:58
User entered '03 Sep 2020 15:17'	System	03 Sep 2020 22:17:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 15:06'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 17:36'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:55', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:26:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:05', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:07', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'None (0)'	System	04 Sep 2020 03:27:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered 'No (N)'	System	04 Sep 2020 03:27:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-03T20:27:20', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ac1a7a40-e577-4bf6-8a3b-498f8d75ba30'	System	04 Sep 2020 03:27:24
User entered '03 Sep 2020 20:27'	System	04 Sep 2020 03:27:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '03 Sep 2020 18:31'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 2'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'None (0)'	System	05 Sep 2020 02:28:19

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'No interference with activity (1)'	System	05 Sep 2020 02:28:19

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:54', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'None (0)'	System	05 Sep 2020 02:28:19

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:27:57', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'None (0)'	System	05 Sep 2020 02:28:19

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:28:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'None (0)'	System	05 Sep 2020 02:28:19

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:28:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'None (0)'	System	05 Sep 2020 02:28:19

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:28:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered 'No (N)'	System	05 Sep 2020 02:28:19

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-04T19:28:17', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '44e4a45c-5385-4208-8b0d-a76f20dae9f6'	System	05 Sep 2020 02:28:19
User entered '04 Sep 2020 19:28'	System	05 Sep 2020 02:28:19

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 3'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:28', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:33', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:43', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'None (0)'	System	06 Sep 2020 02:30:55

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered 'No (N)'	System	06 Sep 2020 02:30:55

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-05T19:30:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '29d2484f-9e61-4ead-a8b1-08827513bd71'	System	06 Sep 2020 02:30:55
User entered '05 Sep 2020 19:30'	System	06 Sep 2020 02:30:55

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 4'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:01', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9'	System	07 Sep 2020 03:53:24
User entered 'None (0)'	System	07 Sep 2020 03:53:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9'	System	07 Sep 2020 03:53:24
User entered 'None (0)'	System	07 Sep 2020 03:53:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:06', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9' User entered 'None (0)'	System	07 Sep 2020 03:53:24
	System	07 Sep 2020 03:53:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9' User entered 'None (0)'	System	07 Sep 2020 03:53:24
	System	07 Sep 2020 03:53:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9' User entered 'None (0)'	System	07 Sep 2020 03:53:24
	System	07 Sep 2020 03:53:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9'	System	07 Sep 2020 03:53:24
User entered 'None (0)'	System	07 Sep 2020 03:53:24

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:18', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9'	System	07 Sep 2020 03:53:24
User entered 'No (N)'	System	07 Sep 2020 03:53:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-06T20:53:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0f683709-fa9c-43f4-adca-d5ad819712e9'	System	07 Sep 2020 03:53:24
User entered '06 Sep 2020 20:53'	System	07 Sep 2020 03:53:24

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 5'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:27', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:32', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:37', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'None (0)'	System	08 Sep 2020 02:35:49

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered 'No (N)'	System	08 Sep 2020 02:35:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-07T19:35:47', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'c7e55edb-6447-4005-bef4-1fc04f924dec'	System	08 Sep 2020 02:35:49
User entered '07 Sep 2020 19:35'	System	08 Sep 2020 02:35:49

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 6'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:28', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:31', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:34', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:40', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'None (0)'	System	09 Sep 2020 04:47:52

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:48', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered 'No (N)'	System	09 Sep 2020 04:47:52

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-08T21:47:51', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'eab6876f-91cf-4a19-998e-68d1f3448655'	System	09 Sep 2020 04:47:52
User entered '08 Sep 2020 21:47'	System	09 Sep 2020 04:47:52

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	03 Sep 2020 21:50:07
User entered 'Day 7'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:30', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'None (0)'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:35', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'No interference with activity (1)'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'None (0)'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:41', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'None (0)'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'None (0)'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'None (0)'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered 'No (N)'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-09-09T20:10:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '291380e2-b15b-4576-8d57-e83150b8aee6'	System	10 Sep 2020 03:10:56
User entered '09 Sep 2020 20:10'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:50:07

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	10 Sep 2020 03:10:56
User entered 'Day 8'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:29:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	10 Sep 2020 03:10:56
User entered 'Day 9'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

US3162072

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:29:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	10 Sep 2020 03:10:56
User entered 'Day 8'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	10 Sep 2020 03:10:56
User entered 'Day 9'	System	10 Sep 2020 03:10:56

US3162072

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:29:54

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 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:29:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 03:10:56

**US3162072**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:09
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:08:23

**US3162072**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:09
User entered '10 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:08:23

**US3162072**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:09
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:08:23

**US3162072**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:09
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:08:23

US3162072

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:08:32

**US3162072**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	11 Sep 2020 18:08:32

**US3162072**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	18 Sep 2020 15:21:31

**US3162072**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:18
User entered '17 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	18 Sep 2020 15:21:31

**US3162072**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:18
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	18 Sep 2020 15:21:31

US3162072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:18
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	18 Sep 2020 15:21:31

US3162072

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:23
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	18 Sep 2020 15:21:56

**US3162072**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	18 Sep 2020 15:21:56

**US3162072**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:36
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	25 Sep 2020 15:17:26

**US3162072**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:36
User entered '24 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	25 Sep 2020 15:17:26

US3162072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:36
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	25 Sep 2020 15:17:26

**US3162072**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:36
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	25 Sep 2020 15:17:26

US3162072

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:37:40
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	25 Sep 2020 15:17:33

**US3162072**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	25 Sep 2020 15:17:33

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:38:05
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:10

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:38:05
User entered '1 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:10

US3162072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:38:05
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:10

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'VISIT3'	System	02 Oct 2020 03:31:10

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '1 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '13:58'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '1 Oct 2020 13:58'	System	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '97.1' F	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '75'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'bpm'	System	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '15'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'breaths/min'	System	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '129'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	02 Oct 2020 03:31:37

US3162072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:02
User entered '76'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'mmHg'	System	02 Oct 2020 03:31:37

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58

US3162072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:45
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:42

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:45
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:42

US3162072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:59
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:52

US3162072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:59
User entered '1 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:52

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:49:59
User entered '14:07'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:52

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '1 Oct 2020 14:07'	System	02 Oct 2020 03:31:52

US3162072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 23:50:05
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Oct 2020 03:31:55

**US3162072**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered '1'	System	02 Oct 2020 03:31:55

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 64'	System	06 Aug 2020 22:56:56

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-08T18:55:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '548d5b66-da6a-4ae8-8dee-9dccaab36b97'	System	09 Oct 2020 01:56:22
User entered 'No (N)'	System	09 Oct 2020 01:56:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-08T18:55:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '548d5b66-da6a-4ae8-8dee-9dccaab36b97'	System	09 Oct 2020 01:56:22
User entered 'No (N)'	System	09 Oct 2020 01:56:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-08T18:56:19', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '548d5b66-da6a-4ae8-8dee-9dccaab36b97'	System	09 Oct 2020 01:56:22
User entered '08 Oct 2020 18:56:19'	System	09 Oct 2020 01:56:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 71'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-15T19:23:47', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3158a2c8-9af7-4d39-8d2a-4cb8eaafec2d'	System	16 Oct 2020 02:24:06
User entered 'No (N)'	System	16 Oct 2020 02:24:06

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-15T19:23:57', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3158a2c8-9af7-4d39-8d2a-4cb8eaafec2d'	System	16 Oct 2020 02:24:06
User entered 'No (N)'	System	16 Oct 2020 02:24:06

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-15T19:24:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3158a2c8-9af7-4d39-8d2a-4cb8eaafec2d' User entered '15 Oct 2020 19:24:02'	System	16 Oct 2020 02:24:06
	System	16 Oct 2020 02:24:06

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 78'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-22T09:04:24', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '983e0329-9451-48ea-b160-30a3a4ac5e48'	System	22 Oct 2020 16:04:50
User entered 'No (N)'	System	22 Oct 2020 16:04:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-22T09:04:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '983e0329-9451-48ea-b160-30a3a4ac5e48'	System	22 Oct 2020 16:04:50
User entered 'No (N)'	System	22 Oct 2020 16:04:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-10-22T09:04:44', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '983e0329-9451-48ea-b160-30a3a4ac5e48'	System	22 Oct 2020 16:04:50
User entered '22 Oct 2020 09:04:44'	System	22 Oct 2020 16:04:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 92'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-05T08:11:53', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07a47228-24c3-4230-99b5-1c2676c610d0'	System	05 Nov 2020 16:12:11
User entered 'No (N)'	System	05 Nov 2020 16:12:11

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-05T08:12:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07a47228-24c3-4230-99b5-1c2676c610d0'	System	05 Nov 2020 16:12:11
User entered 'No (N)'	System	05 Nov 2020 16:12:11

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-05T08:12:10', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '07a47228-24c3-4230-99b5-1c2676c610d0'	System	05 Nov 2020 16:12:11
User entered '05 Nov 2020 08:12:10'	System	05 Nov 2020 16:12:11

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 99'	System	06 Aug 2020 22:56:56

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

[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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:13:50', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'Yes (Y)'	System	12 Nov 2020 16:15:35

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:13:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'No (N)'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:07', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'Yes (Y)'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43' User entered '0'	System	12 Nov 2020 16:15:35
	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '1'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43' User entered '0'	System	12 Nov 2020 16:15:35
	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '1'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '1'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43' User entered '0'	System	12 Nov 2020 16:15:35
	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:14:58', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '0'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:15:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 16:15:35

US3162072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:15:12', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'Yes (Y)'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:15:15', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-12T08:15:25', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'b4eb0f55-55ab-4167-a211-a156cb720a43'	System	12 Nov 2020 16:15:35
User entered '12 Nov 2020 08:15:25'	System	12 Nov 2020 16:15:35

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered 'Day 106'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-19T06:27:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '71bbee36-e360-43db-a2df-30ba775b8d39'	System	19 Nov 2020 14:28:08
User entered 'No (N)'	System	19 Nov 2020 14:28:08

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-19T06:27:56', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '71bbee36-e360-43db-a2df-30ba775b8d39'	System	19 Nov 2020 14:28:08
User entered 'No (N)'	System	19 Nov 2020 14:28:08

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-19T06:28:04', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '71bbee36-e360-43db-a2df-30ba775b8d39'	System	19 Nov 2020 14:28:08
User entered '19 Nov 2020 06:28:04'	System	19 Nov 2020 14:28:08

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:58
Data entry locked.	System	06 Aug 2020 22:56:56
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 22:56:56

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-11-25T15:09:39', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '4ea2b61e-ebbf-4783-b7ba-e704ff3821ea'	System	25 Nov 2020 23:10:07
User entered 'No (N)'	System	25 Nov 2020 23:10:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-11-25T15:09:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '4ea2b61e-ebbf-4783-b7ba-e704ff3821ea'	System	25 Nov 2020 23:10:07
User entered 'No (N)'	System	25 Nov 2020 23:10:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-11-25T15:10:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '4ea2b61e-ebbf-4783-b7ba-e704ff3821ea' User entered '25 Nov 2020 15:10:00'	System	25 Nov 2020 23:10:07
	System	25 Nov 2020 23:10:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-12-02T13:09:57', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8114ec10-c2e7-4af3-b724-2e84202493dc'	System	02 Dec 2020 21:10:22
User entered 'No (N)'	System	02 Dec 2020 21:10:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-12-02T13:10:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8114ec10-c2e7-4af3-b724-2e84202493dc'	System	02 Dec 2020 21:10:22
User entered 'No (N)'	System	02 Dec 2020 21:10:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-12-02T13:10:20', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8114ec10-c2e7-4af3-b724-2e84202493dc'	System	02 Dec 2020 21:10:22
User entered '02 Dec 2020 13:10:20'	System	02 Dec 2020 21:10:22

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-12-08T11:07:02', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd48d4885-9f14-40df-87b5-f8bd05052162'	System	08 Dec 2020 19:07:25
User entered 'No (N)'	System	08 Dec 2020 19:07:25

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-12-08T11:07:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd48d4885-9f14-40df-87b5-f8bd05052162'	System	08 Dec 2020 19:07:25
User entered 'No (N)'	System	08 Dec 2020 19:07:25

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-12-08T11:07:21', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'd48d4885-9f14-40df-87b5-f8bd05052162'	System	08 Dec 2020 19:07:25
User entered '08 Dec 2020 11:07:21'	System	08 Dec 2020 19:07:25

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-12-14T14:00:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff88999a-4d8e-4741-9ef3-f05249d5cf3f'	System	14 Dec 2020 22:00:14
User entered 'No (N)'	System	14 Dec 2020 22:00:14

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-12-14T14:00:08', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff88999a-4d8e-4741-9ef3-f05249d5cf3f'	System	14 Dec 2020 22:00:14
User entered 'No (N)'	System	14 Dec 2020 22:00:14

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-12-14T14:00:12', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'ff88999a-4d8e-4741-9ef3-f05249d5cf3f' User entered '14 Dec 2020 14:00:12'	System	14 Dec 2020 22:00:14
	System	14 Dec 2020 22:00:14

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-12-22T07:12:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '95b4b813-b294-4df7-a972-7e484fe51ec0'	System	22 Dec 2020 15:12:17
User entered 'No (N)'	System	22 Dec 2020 15:12:17

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-12-22T07:12:07', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '95b4b813-b294-4df7-a972-7e484fe51ec0'	System	22 Dec 2020 15:12:17
User entered 'No (N)'	System	22 Dec 2020 15:12:17

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-12-22T07:12:13', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '95b4b813-b294-4df7-a972-7e484fe51ec0' User entered '22 Dec 2020 07:12:13'	System	22 Dec 2020 15:12:17
	System	22 Dec 2020 15:12:17

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2020-12-28T12:26:32', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3de60616-e0f6-43ac-9dec-f026f8fd8bf8'	System	28 Dec 2020 20:26:47
User entered 'No (N)'	System	28 Dec 2020 20:26:47

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2020-12-28T12:26:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3de60616-e0f6-43ac-9dec-f026f8fd8bf8'	System	28 Dec 2020 20:26:47
User entered 'No (N)'	System	28 Dec 2020 20:26:47

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2020-12-28T12:26:42', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '3de60616-e0f6-43ac-9dec-f026f8fd8bf8' User entered '28 Dec 2020 12:26:42'	System	28 Dec 2020 20:26:47
	System	28 Dec 2020 20:26:47

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-01-04T16:49:01', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '18a4b813-03c6-40be-9708-40c08ce42f1c'	System	05 Jan 2021 00:49:20
User entered 'No (N)'	System	05 Jan 2021 00:49:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-01-04T16:49:11', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '18a4b813-03c6-40be-9708-40c08ce42f1c'	System	05 Jan 2021 00:49:20
User entered 'No (N)'	System	05 Jan 2021 00:49:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-01-04T16:49:19', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '18a4b813-03c6-40be-9708-40c08ce42f1c'	System	05 Jan 2021 00:49:20
User entered '04 Jan 2021 16:49:19'	System	05 Jan 2021 00:49:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-01-11T13:15:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '396afa9c-96cd-41ab-9782-d535769f1fdd'	System	11 Jan 2021 21:16:01
User entered 'No (N)'	System	11 Jan 2021 21:16:01

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-01-11T13:15:51', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '396afa9c-96cd-41ab-9782-d535769f1fdd'	System	11 Jan 2021 21:16:01
User entered 'No (N)'	System	11 Jan 2021 21:16:01

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-01-11T13:15:56', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '396afa9c-96cd-41ab-9782-d535769f1fdd' User entered '11 Jan 2021 13:15:56'	System	11 Jan 2021 21:16:01
	System	11 Jan 2021 21:16:01

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-01-18T17:30:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'fc058dbf-6dd8-47b7-a7c0-789d963bc48a'	System	19 Jan 2021 01:30:20
User entered 'No (N)'	System	19 Jan 2021 01:30:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-01-18T17:30:09', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'fc058dbf-6dd8-47b7-a7c0-789d963bc48a'	System	19 Jan 2021 01:30:20
User entered 'No (N)'	System	19 Jan 2021 01:30:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-01-18T17:30:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'fc058dbf-6dd8-47b7-a7c0-789d963bc48a' User entered '18 Jan 2021 17:30:14'	System	19 Jan 2021 01:30:20

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-01-26T06:58:28', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '47f70cfc-4d56-4951-b384-3f7ed82a9d43'	System	26 Jan 2021 14:59:07
User entered 'No (N)'	System	26 Jan 2021 14:59:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-01-26T06:58:36', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '47f70cfc-4d56-4951-b384-3f7ed82a9d43'	System	26 Jan 2021 14:59:07
User entered 'No (N)'	System	26 Jan 2021 14:59:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-01-26T06:58:43', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '47f70cfc-4d56-4951-b384-3f7ed82a9d43' User entered '26 Jan 2021 06:58:43'	System	26 Jan 2021 14:59:07

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-02-02T11:09:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '35791e19-3498-4f3f-b135-573cb3e8618d'	System	02 Feb 2021 19:09:50
User entered 'No (N)'	System	02 Feb 2021 19:09:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-02-02T11:09:41', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '35791e19-3498-4f3f-b135-573cb3e8618d'	System	02 Feb 2021 19:09:50
User entered 'No (N)'	System	02 Feb 2021 19:09:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-02-02T11:09:45', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '35791e19-3498-4f3f-b135-573cb3e8618d'	System	02 Feb 2021 19:09:50
User entered '02 Feb 2021 11:09:45'	System	02 Feb 2021 19:09:50

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-02-09T12:05:14', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '19a69420-ca40-4caf-9657-7fe7e552bfb0'	System	09 Feb 2021 20:05:32
User entered 'No (N)'	System	09 Feb 2021 20:05:32

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-02-09T12:05:26', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '19a69420-ca40-4caf-9657-7fe7e552bfb0'	System	09 Feb 2021 20:05:32
User entered 'No (N)'	System	09 Feb 2021 20:05:32

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-02-09T12:05:29', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '19a69420-ca40-4caf-9657-7fe7e552bfb0'	System	09 Feb 2021 20:05:32
User entered '09 Feb 2021 12:05:29'	System	09 Feb 2021 20:05:32

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-02-15T13:00:52', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8f524bd7-b7e6-4f76-b14a-d230e1261002'	System	15 Feb 2021 21:01:09
User entered 'No (N)'	System	15 Feb 2021 21:01:09

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-02-15T13:01:03', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8f524bd7-b7e6-4f76-b14a-d230e1261002'	System	15 Feb 2021 21:01:09
User entered 'No (N)'	System	15 Feb 2021 21:01:09

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-02-15T13:01:06', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '8f524bd7-b7e6-4f76-b14a-d230e1261002'	System	15 Feb 2021 21:01:09
User entered '15 Feb 2021 13:01:06'	System	15 Feb 2021 21:01:09

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:23:28

**US3162072**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-02-22T13:00:38', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a5f46804-f573-440e-b766-0dfc1f32a8d7'	System	22 Feb 2021 21:00:52
User entered 'No (N)'	System	22 Feb 2021 21:00:52

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-02-22T13:00:46', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a5f46804-f573-440e-b766-0dfc1f32a8d7'	System	22 Feb 2021 21:00:52
User entered 'No (N)'	System	22 Feb 2021 21:00:52

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-02-22T13:00:49', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'a5f46804-f573-440e-b766-0dfc1f32a8d7'	System	22 Feb 2021 21:00:52
User entered '22 Feb 2021 13:00:49'	System	22 Feb 2021 21:00:52

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-03-01T15:55:27-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af4339df-f09f-428c-b584-dae68392fc1e' User entered 'No (N)'	System	01 Mar 2021 23:55:45
	System	01 Mar 2021 23:55:45

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-03-01T15:55:37-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af4339df-f09f-428c-b584-dae68392fc1e'	System	01 Mar 2021 23:55:45
User entered 'No (N)'	System	01 Mar 2021 23:55:45

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-01T15:55:42-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'af4339df-f09f-428c-b584-dae68392fc1e' User entered '01 Mar 2021 15:55:42'	System	01 Mar 2021 23:55:45
	System	01 Mar 2021 23:55:45

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-03-08T18:31:25-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7890e617-16a2-4f15-9beb-cf613c4e086f'	System	09 Mar 2021 02:39:29
User entered 'No (N)'	System	09 Mar 2021 02:39:29

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-03-08T18:31:32-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7890e617-16a2-4f15-9beb-cf613c4e086f'	System	09 Mar 2021 02:39:29
User entered 'No (N)'	System	09 Mar 2021 02:39:29

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-08T18:31:35-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '7890e617-16a2-4f15-9beb-cf613c4e086f' User entered '08 Mar 2021 18:31:35'	System	09 Mar 2021 02:39:29

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-03-24T08:27:17-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc' User entered 'Yes (Y)'	System	24 Mar 2021 15:28:00
	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-03-24T08:27:21-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc' User entered 'No (N)'	System	24 Mar 2021 15:28:00
	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-24T08:27:25-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc' User entered 'No (N)'	System	24 Mar 2021 15:28:00
	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-24T08:27:30-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc' User entered 'Yes (Y)'	System	24 Mar 2021 15:28:00
	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Please 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 (66eff834c8006885)', Time: '2021-03-24T08:27:38-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc'	System	24 Mar 2021 15:28:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-24T08:27:48-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e4c54940-e7e6-4c0f-bf60-efc59384acfc' User entered '24 Mar 2021 08:27:48'	System	24 Mar 2021 15:28:00
	System	24 Mar 2021 15:28:00

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-04-05T16:59:57-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0e27f88d-b996-4e7b-9e2b-6df7f695b7ec'	System	06 Apr 2021 00:00:22
User entered 'No (N)'	System	06 Apr 2021 00:00:22

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-04-05T17:00:06-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0e27f88d-b996-4e7b-9e2b-6df7f695b7ec'	System	06 Apr 2021 00:00:22
User entered 'No (N)'	System	06 Apr 2021 00:00:22

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-04-05T17:00:18-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '0e27f88d-b996-4e7b-9e2b-6df7f695b7ec'	System	06 Apr 2021 00:00:22
User entered '05 Apr 2021 17:00:18'	System	06 Apr 2021 00:00:22

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-04-13T09:53:55-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '20285587-e25b-49cb-bd58-9b7285b841dd' User entered 'No (N)'	System	13 Apr 2021 16:54:15
	System	13 Apr 2021 16:54:15

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-04-13T09:54:04-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '20285587-e25b-49cb-bd58-9b7285b841dd'	System	13 Apr 2021 16:54:15
User entered 'No (N)'	System	13 Apr 2021 16:54:15

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-04-13T09:54:09-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: '20285587-e25b-49cb-bd58-9b7285b841dd'	System	13 Apr 2021 16:54:15
User entered '13 Apr 2021 09:54:09'	System	13 Apr 2021 16:54:15

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-04-19T08:55:17-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e5e0462b-d9ef-4fc8-8583-082c37977c6f'	System	19 Apr 2021 15:55:37
User entered 'No (N)'	System	19 Apr 2021 15:55:37

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-04-19T08:55:25-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e5e0462b-d9ef-4fc8-8583-082c37977c6f'	System	19 Apr 2021 15:55:37
User entered 'No (N)'	System	19 Apr 2021 15:55:37

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-04-19T08:55:32-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'e5e0462b-d9ef-4fc8-8583-082c37977c6f' User entered '19 Apr 2021 08:55:32'	System	19 Apr 2021 15:55:37
	System	19 Apr 2021 15:55:37

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[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 (66eff834c8006885)', Time: '2021-04-26T12:33:02-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'cbcf2d3e-b639-4ce7-9088-92f851b696ec'	System	26 Apr 2021 19:33:20
User entered 'No (N)'	System	26 Apr 2021 19:33:20

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

Have you been exposed to someone with 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 (66eff834c8006885)', Time: '2021-04-26T12:33:12-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'cbcf2d3e-b639-4ce7-9088-92f851b696ec'	System	26 Apr 2021 19:33:20
User entered 'No (N)'	System	26 Apr 2021 19:33:20

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-04-26T12:33:16-07:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'cbcf2d3e-b639-4ce7-9088-92f851b696ec' User entered '26 Apr 2021 12:33:16'	System	26 Apr 2021 19:33:20
	System	26 Apr 2021 19:33:20

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:28
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:23:28

**US3162072**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:29:54**

[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 18:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-08T18:31:11-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'cd500179-7878-42e0-b75e-95d3efee3102'	System	09 Mar 2021 02:39:20
User entered 'No (N)'	System	09 Mar 2021 02:39:20

**US3162072**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (66eff834c8006885)', Time: '2021-03-08T18:31:16-08:00', User OID: 'PatientReportedOutcome (US3162072)', ODM File OID: 'cd500179-7878-42e0-b75e-95d3efee3102'	System	09 Mar 2021 02:39:20
User entered '08 Mar 2021 18:31:16'	System	09 Mar 2021 02:39:20

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:31:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 21:37:23

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:31:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered '29 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 21:37:23

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:31:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 21:37:23

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:31:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 21:37:23

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:32:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 21:37:30

**US3162072**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:58
User entered 'I'	System	30 Oct 2020 21:37:30

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:33:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:23:45

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:33:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '3 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:23:45

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:33:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:23:45

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:33:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:23:45

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:34:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:24:00

**US3162072**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
User entered 'I'	System	04 Dec 2020 18:24:00

**US3162072**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 17:29:50

**US3162072**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '31 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 17:29:50

**US3162072**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 17:29:50

US3162072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 17:29:50

**US3162072**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:35:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 17:29:55

**US3162072**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
User entered 'I'	System	05 Jan 2021 17:29:55

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:36:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:46:07

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:36:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '31 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:46:07

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:36:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:46:07

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:36:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:46:07

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 22:37:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:46:13

**US3162072**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:45:17
User entered 'I'	System	02 Feb 2021 19:46:13

US3162072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:30:20
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:46:44

US3162072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:30:20
User entered '2 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:46:44

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:30:20
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:46:44

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'VISIT4'	System	04 Mar 2021 16:46:44

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '2 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '13:45'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered '2 Mar 2021 13:45'	System	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '98' F	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '70'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'bpm'	System	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '15'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'breaths/min'	System	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '140'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'mmHg'	System	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:31:48
User entered '80'	(b) (4), (b) (6)	30 Mar 2021 19:46:04

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'mmHg'	System	30 Mar 2021 19:46:04

US3162072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43

US3162072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:32:00
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:00

US3162072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:32:00
User entered empty.	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:00

US3162072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:31:57
User closed query 'Since blood work was done on Mar 2, in combined with OL-D29, please enter that data on this page as well.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:29:34
Query 'Since blood work was done on Mar 2, in combined with OL-D29, please enter that data on this page as well.' answered with 'updated, per query request ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 00:18:31
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Apr 2021 00:18:04
User opened query 'Since blood work was done on Mar 2, in combined with OL-D29, please enter that data on this page as well.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:38:24
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:21

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

**Collection date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:31:57
User entered '2 Mar 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Apr 2021 00:18:04
User entered empty.	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:21

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:31:57
User entered '14:29' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Apr 2021 00:18:04
User entered empty.	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:21

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered '2 Mar 2021 14:29'	System	13 Apr 2021 00:18:04
User entered empty.	System	04 Mar 2021 16:47:21

US3162072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:39:48
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Mar 2021 16:47:28

**US3162072**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:43
User entered 'I'	System	04 Mar 2021 16:47:28

**US3162072**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 16:58:36

**US3162072**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

**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 23:00:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 16:58:36

**US3162072**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[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 23:00:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Apr 2021 16:58:36

**US3162072**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:58:36

US3162072

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 17:00:28

**US3162072**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 17:00:28

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:02:02
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 00:57:42

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:29:54**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:02:02
User entered '09:45'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 00:57:42

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:29:54**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '9 Nov 2020 09:45'	System	10 Nov 2020 00:57:42

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:02:02
User entered 'Safety Call (Safety Call)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 00:57:42

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:29:54**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:02:02
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 00:57:42

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Day 1 (Day 1)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '8 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:05:49
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:59
	(b) (4)	
User closed query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:37:11
Query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' answered with 'Not done' (Site from DM).	Judith Kirstein (b) (4)	23 Jan 2021 05:56:17
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Jan 2021 05:55:49
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4)	23 Jan 2021 05:55:49
	(b) (4)	
User opened query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:51:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered empty.	Judith Kirstein (b) (4)	10 Nov 2020 01:00:21
	(b) (4)	

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '%'	System	23 Jan 2021 05:55:49
User entered empty.	System	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '100.3' F	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:00:21

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Day 2 (Day 2)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '99'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 15:29:54**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '%'	System	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '99.3' F	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:46:38
User closed query 'Source documents note Runny Nose as Moderate. Please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 19:46:36
Query 'Source documents note Runny Nose as Moderate. Please verify. Thank you.' answered with 'corrected' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 05:56:42
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 05:56:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Jan 2021 05:56:32
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User opened query 'Source documents note Runny Nose as Moderate. Please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 00:06:08
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:03

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Day 3 (Day 3)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '10 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '0'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '100'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 15:29:54**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '%'	System	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '97.7' F	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 05:33:36

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:59
	(b) (4)	
User entered 'Day 4 (Day 4)'	Judith Kirstein (b) (4)	11 Nov 2020 20:42:34
	(b) (4)	

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '11 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '0'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered missing code ND - Not Done.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 15:29:54**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '%'	System	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered '97.2' F	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:29
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:34

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:29:54**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:42:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 20:42:52
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:42:52
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 01:03:50
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

US3162072

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:03:17
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:03:50

**US3162072**

**Folder: Covid-19 Assessment 09 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:29:54**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:20:06
User entered '0'	System	11 Nov 2020 20:42:52

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 3 (Day 3)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered '11 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 5 (Day 5)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

US3162072

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 7 (Day 7)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

US3162072

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 14 (Day 14)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 21 (Day 21)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User accepted default value 'Day 28 (Day 28)'	Judith Kirstein (b) (4)	11 Nov 2020 22:49:29
	(b) (4)	

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered 'NA (COVID-19 Negative) (NA)'	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

**US3162072**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:12:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 22:49:29

US3162072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:46
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:05:11

US3162072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:46
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:05:11

US3162072

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:54

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 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:07:46
User entered 'Clinic (Clinic)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:05:11

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered 'SICKD1'	System	10 Nov 2020 01:05:11

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '11:19'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered '9 Nov 2020 11:19'	System	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '71' in	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31
DataPoint set to visible.	System	10 Nov 2020 01:05:11

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '197.4' lb	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31
DataPoint set to visible.	System	10 Nov 2020 01:05:11

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '99.3' F	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered 'Oral (Oral)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '73'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered 'bpm'	System	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '15'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered 'breaths/min'	System	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '146'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered 'mmHg'	System	10 Nov 2020 01:06:31

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:36
User entered '86'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User entered 'mmHg'	System	10 Nov 2020 01:06:31

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08

US3162072

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08

US3162072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:49
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:45

US3162072

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:49
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:06:45

US3162072

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:29:54

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:59
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:07:02

**US3162072**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:10:59
User entered '9 Nov 2020'	Judith Kirstein (b) (4) (b) (4)	10 Nov 2020 01:07:02

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:03:33

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:03:33

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:03:33

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 19:03:33

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User entered '0'	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 21:27:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:15:04

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 21:27:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:15:04

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:45:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '1'	System	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'I'	System	02 Feb 2021 19:04:26

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:43
User closed query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).		13 Apr 2021 23:28:41
Query 'If height and weight were not done during this visit, please remove the data. Thank you.' answered with 'updated. height and weight were not collect during visit. ' (Site from CRA).		13 Apr 2021 00:14:22
Signature has been broken.		13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error		13 Apr 2021 00:13:48
DataPoint Un-verified.		12 Apr 2021 23:47:53
DataPoint Verified.		12 Apr 2021 23:47:50
User opened query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).		12 Apr 2021 23:47:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '71' in	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:45
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 00:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:29:54**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered empty.	System	13 Apr 2021 00:13:48
User entered '25.15740'	System	03 Feb 2021 17:41:29
DataPoint set to visible.	System	02 Feb 2021 19:04:26

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:43
User closed query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:28:41
Query 'If height and weight were not done during this visit, please remove the data. Thank you.' answered with 'updated. height and weight were not collect during visit. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 00:14:22
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 00:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User opened query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:47:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '71' in	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:45
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 00:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:29:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered empty.	System	13 Apr 2021 00:13:48
User entered '25.15740'	System	03 Feb 2021 17:41:29
DataPoint set to visible.	System	02 Feb 2021 19:04:26

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '09:01'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Feb 2021 09:01'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '97.2' F	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '74'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'bpm'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '12'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'breaths/min'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '133'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '85'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:43
User closed query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:28:41
Query 'If height and weight were not done during this visit, please remove the data. Thank you.' answered with 'updated. height and weight were not collect during visit. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 00:14:22
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 00:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User opened query 'If height and weight were not done during this visit, please remove the data. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 23:47:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '71' in	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 23:28:45
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 00:13:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 00:13:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '180' lb	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:29:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered empty.	System	13 Apr 2021 00:13:48
User entered '25.15740'	System	03 Feb 2021 17:41:29
DataPoint set to visible.	System	02 Feb 2021 19:04:26

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '10:50'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Feb 2021 10:50'	System	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '97.9' F	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '66'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'bpm'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '12'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'breaths/min'	System	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '134'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Feb 2021 17:41:29

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:47:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '90'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Feb 2021 17:41:29

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:01

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:01

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mRNA-1273'	System	02 Feb 2021 19:05:02
DataPoint set to visible.	System	02 Feb 2021 19:04:26

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '10:15'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Feb 2021 10:15'	System	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:02

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:14
User entered 'ONCE'	System	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 19:05:02

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:15

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:15

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:59:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '09:02'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:15

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Feb 2021 09:02'	System	03 Feb 2021 17:42:15

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:00:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:32

US3162072

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:00:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '2 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:32

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:00:11
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered '09:04'	Tiffany Williams (b) (4) (b) (4)	03 Feb 2021 17:42:32

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:54**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Feb 2021 09:04'	System	03 Feb 2021 17:42:32

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:00:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 19:05:13

**US3162072**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'I'	System	02 Feb 2021 19:05:13

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:01:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 18:40:58

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:01:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered '9 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 18:40:58

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:01:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 18:40:58

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:01:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered empty.	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 18:40:58

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:01:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:03:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 18:41:05

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'I'	System	11 Feb 2021 18:41:05

**US3162072**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '1'	System	11 Feb 2021 18:41:05
DataPoint set to visible.	System	11 Feb 2021 18:41:05

**US3162072**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:05
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:02:17

**US3162072**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:05
User entered '2 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:02:17

**US3162072**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:05
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:02:17

**US3162072**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'OLD29'	System	03 Mar 2021 01:02:17

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4)	03 Mar 2021 01:04:31
	(b) (4)	

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '2 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '13:45'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Mar 2021 13:45'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '98.0' F	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '70'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'bpm'	System	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '15'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'breaths/min'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '140'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '80'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '2 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '16:07'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Mar 2021 16:07'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '98.8' F	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '61'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'bpm'	System	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '12'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'breaths/min'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '139'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Mar 2021 01:04:31

US3162072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:38
User entered '88'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mmHg'	System	03 Mar 2021 01:04:31

**US3162072**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:53
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:50

**US3162072**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:02:53
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:04:50

US3162072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User closed query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM). Query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' answered with 'Per IRT Confirmation email at 15:1 on 02MAR2021 this is correct as is. ' (Site from DM). User opened query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 21:16:01  14 Apr 2021 19:41:17  14 Apr 2021 08:58:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

US3162072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

US3162072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered empty.	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'mRNA-1273'	System	03 Mar 2021 01:05:10
DataPoint set to visible.	System	11 Feb 2021 18:41:05

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered '2 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered '15:32'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered '2 Mar 2021 15:32'	System	03 Mar 2021 01:05:10

US3162072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:10

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:19
User entered 'ONCE'	System	03 Mar 2021 01:05:10

**US3162072**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 01:05:10

US3162072

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 00:03:25
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	03 Mar 2021 01:05:15

**US3162072**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'I'	System	03 Mar 2021 01:05:15

**US3162072**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:28:38
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:53:02

US3162072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:28:38
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 13:56:36
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PER SOURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:53:54
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Mar 2021 17:53:02
User entered '13 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:53:02

**US3162072**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:28:38
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:53:02

**US3162072**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:28:38
User entered empty.	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:53:02

**US3162072**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:28:47
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	16 Mar 2021 17:54:02

**US3162072**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:31
User entered 'I'	System	16 Mar 2021 17:54:02

**US3162072**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 23:29:04

**US3162072**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 23:29:04

**US3162072**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Apr 2021 23:29:04

**US3162072**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	02 Apr 2021 23:29:04

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 23:29:31

US3162072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 23:29:31

US3162072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 23:29:31

**US3162072**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 23:29:40

US3162072

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 23:29:40

**US3162072**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 23:30:12

**US3162072**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 23:30:12

**US3162072**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User entered '13:52'	(b) (4), (b) (6)	02 Apr 2021 23:30:12

**US3162072**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 13:52'	System	02 Apr 2021 23:30:12

US3162072

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:29:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 16:53:06
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:53:06
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:14:46
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:30

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 13:01:19

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:18:38
Data point term sent to Coder	System	11 Nov 2020 17:01:01
User entered 'Acute viral infection, unspecified'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:43:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 20:43:41
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:43:41
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:00:24
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '8 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User entered empty.	System	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:43:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '10 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:43:41
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User entered empty.	System	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:33:45
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:01:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:01:18
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:02:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Nov 2020 21:01:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'l'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

US3162072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	11 Nov 2020 20:43:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:19:10
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User entered '0'	System	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:19
User entered 'I'	System	11 Nov 2020 17:00:24

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 13:01:19

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 13:00:21

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:32:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:32:38
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:17:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:17:39
Data point term sent to Coder	System	24 Mar 2021 18:17:14
User entered 'angina'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered '15 Oct 2020'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User entered empty.	System	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:11:35
User entered '14 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:11:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '12 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User entered empty.	System	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'None (NONE)'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		06 Apr 2021 00:06:47
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	06 Apr 2021 00:06:27
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:27
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:48:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Error corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:07:05
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:12
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '1'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2062 of 2865

US3162072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:47
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:06:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '1'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	24 Mar 2021 18:16:14
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Subject had experienced mild angina starting mid-October 2020 but did not contact his PCP until it worsened. This led to his having 5vessel coronary bypass surgery on 12MAR2021. See AE#3'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User entered '0'	System	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21
User entered 'I'	System	24 Mar 2021 18:16:14

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:00:21

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:26:58
User entered 'USA-US074-2021-mRNA-1273-P301000020'	System	25 Mar 2021 14:26:28
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 14:26:28

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:38:41
Query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'No overlap. AE #2 is mild angina where as AE#3 is unstable angina (worsened), per PI' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 17:46:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User opened query 'Per DM CLR: Please note this AE overlaps with AE #2. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:48:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina unstable, LLT: Crescendo angina - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:41:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:41:40
Data point term sent to Coder	System	24 Mar 2021 18:41:09
User entered 'crescendo angina'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '15 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '12 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '11 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '23 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '3'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	24 Mar 2021 18:40:27
	(b) (4)	

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:38:45
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'con med log updated, per eSource' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 23:43:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:48:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:40:27

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:55:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:01:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'See narrative' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	17 Apr 2021 04:05:26
User entered 'SUBJECT HAD ONSET OF ANGINA IN MID-OCTOBER 2020. IT WORSENERD 15FEB BUT HE DID NOT SEEK MEDICAL CARE UNTIL 04MAR2021, WHEN HE HAD TELEMEDICINE VISIT WITH PCP. SAW CARDIOLOGIST 10MAR21, ADMITTED TO ONE HOSPITAL WHERE STRESS ECHO SHOWED ST SEGMENT DEPRESSION, AND CAUSED CHEST PAIN, SO HE WAS TRANSFERRED TO ANOTHER HOSPITAL WHERE CORONARY ANGIOGRAPHY SHOWED MULTIVESSEL DISEASE, NECESSITATING 5 VESSEL CORONARY BYPASS ON 12MAR21. DURING THAT STAY, HE HAD ANOTHER SAE (AE#4), BILATERAL PNEUMOTHORAX WHEN HIS CHEST TUBES WERE REMOVED, WHICH PROLONGED HIS HOSPITAL STAY TO 23MAR21.' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Apr 2021 04:04:52

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:02:52
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Apr 2021 00:07:48
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	16 Apr 2021 00:07:48
	(b) (4)	
User entered 'SUBJECT HAD ONSET OF ANGINA IN MID-OCTOBER 2020. IT WORSENERD 15FEB BUT HE DID NOT SEEK MEDICAL CARE UNTIL 04MAR2021, WHEN HE HAD TELEMEDICINE VISIT WITH PCP. SAW CARDIOLOGIST 10MAR21, ADMITTED TO ONE HOSPITAL where stress echo showed ST segment depression, and caused chest pain, so he was TRANSFERRED TO ANOTHER hospital WHERE coronary angiography showed multivessel disease, necessitating 5 VESSEL CORONARY BYPASS ON 12MAR21. DURING THAT STAY, HE HAD ANOTHER SAE (AE#4), BILATERAL PNEUMOTHORAX WHEN HIS CHEST TUBES WERE REMOVED, WHICH PROLONGED HIS HOSPITAL STAY TO 23MAR21. See con meds and con procedures' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Apr 2021 00:07:48
	(b) (4)	
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'SARS-CoV-2 PCR test negative on 11MAR2021' (Site from Safety).	Judith Kirstein (b) (4)	16 Apr 2021 00:02:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:05

US3162072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:54

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:07:07
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:06:57
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Subject had onset of angina in mid-October 2020. It worsened 15FEB but he did not seek medical care until 04MAR2021, when he had telemedicine visit with PCP. Saw cardiologist 10MAR21, admitted to one hospital and transferred to another where he underwent 5 vessel coronary bypass on 12MAR21. During that stay, he had another SAE (AE#4), bilateral pneumothorax when his chest tubes were removed, which prolonged his hospital stay to 23MAR21.'	Judith Kirstein (b) (4)	24 Mar 2021 18:40:27
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:40:27

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:32
User entered 'USA-US074-2021-mRNA-1273-P301000020'	(b) (4), (b) (6)	25 Mar 2021 14:27:28

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Pneumothorax - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 23:37:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 23:37:41
Data point term sent to Coder	System	24 Mar 2021 18:52:28
User entered 'Bilateral pneumothorax'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '16 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '23 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '11 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '23 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	24 Mar 2021 18:51:50
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	24 Mar 2021 18:51:50
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

US3162072

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:38:53
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'con procedure log updated, per eSource' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 23:42:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:14
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	24 Mar 2021 18:51:50
	(b) (4)	

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:14
User entered 'Subject underwent 5 vessel coronary bypass on 12MAR21. When chest tubes were removed on 16MAR21, left lung collapsed and right lung partially collapsed. Small chest tubes were inserted to evacuate the air, and this prolonged hospital stay.'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:51:50

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 18:51:50

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:35:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:35:32
Data point term sent to Coder	System	01 Apr 2021 18:33:46
User entered 'coronary artery disease'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '11 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:29:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:29:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:29:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

US3162072

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:29:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered '0'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:12
User entered empty.	Judith Kirstein (b) (4) (b) (4)	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:32:47

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 13:01:23

US3162072

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous conditions NEC, PT: Subcutaneous emphysema, LLT: Subcutaneous emphysema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:45:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:45:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:45
Data point term sent to Coder	System	15 Apr 2021 23:41:45
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:41:01
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 23:41:01
User entered 'Subcutaneous emphysema upper thorax' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:41:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Pneumothorax - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:52:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:52:15
Data point term sent to Coder	System	02 Apr 2021 20:49:44
User entered 'Subcutaneous air right upper thorax from pneumothorax'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '17 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User entered empty.	System	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:51
DataPoint Un-verified.		15 Apr 2021 23:41:01
User entered 'No (N)' reason for change: New Information		15 Apr 2021 23:41:01
DataPoint Verified.		12 Apr 2021 22:50:16
User entered 'Yes (Y)'		02 Apr 2021 20:49:11

US3162072

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:53
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	15 Apr 2021 23:41:16
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	15 Apr 2021 23:41:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Apr 2021 23:41:01
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:41:01
User entered '14 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:41:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User entered empty.	System	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'l'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

US3162072

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:03
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:41:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:41:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:50:16
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User entered '0'	System	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:01:23
User entered 'I'	System	02 Apr 2021 20:49:11

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 13:01:23

US3162072

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Lacunar infarction, LLT: Lacunar infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:12:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:12:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
Data point term sent to Coder	System	15 Apr 2021 22:19:28
User entered 'Acute Lacunar Infarct, left hemisphere'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

US3162072

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '20 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

US3162072

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:25
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 22:19:04

**US3162072**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 22:19:04

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:29:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:11:40
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:44

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:48:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:48:09
Data point term sent to Coder	System	07 Aug 2020 04:46:54
User entered 'vitamin c'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 10:49:39
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	07 Aug 2020 04:46:33
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:46:33

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:46:33

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:49:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:49:11
Data point term sent to Coder	System	07 Aug 2020 04:47:54
User entered 'glucosamine'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '1'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 10:49:48
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	07 Aug 2020 04:47:03
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:47:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:47:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:49:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:49:11
Data point term sent to Coder	System	07 Aug 2020 04:47:54
User entered 'fish oil'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '1'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 10:49:54
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	07 Aug 2020 04:47:27
User entered 'un UNK 2000'	Jared Bradshaw (b) (4)	07 Aug 2020 04:47:27
	(b) (4)	

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:47:27

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:47:27

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:50:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:50:12
Data point term sent to Coder	System	07 Aug 2020 04:48:55
User entered 'multivitamin'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 10:50:00
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	07 Aug 2020 04:47:55
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:47:55

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:47:55

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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)	07 Aug 2020 04:50:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:50:12
Data point term sent to Coder	System	07 Aug 2020 04:48:56
User entered 'lisinopril'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '20'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 10:50:05
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	07 Aug 2020 04:48:21
User entered 'un Jul 2019'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:54:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 22:07:08
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 22:07:08
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Apr 2021 22:07:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:54:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 22:07:08
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 22:07:08
User entered '11 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	02 Apr 2021 22:07:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:13:32
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User entered '1'	System	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User entered '1'	System	07 Aug 2020 04:48:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:13
User entered '804 (804)'	System	07 Aug 2020 04:48:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
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)	11 Nov 2020 23:07:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:07:37
Data point term sent to Coder	System	11 Nov 2020 16:50:42
User entered 'Aspirin'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'acute viral infection, unspecified'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '325'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	14 Nov 2020 20:04:41
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	14 Nov 2020 20:04:41
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	12 Nov 2020 20:29:45
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '8 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:29:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '8 Nov 2020' reason for change: New Information	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 20:04:41
User entered '9 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:29:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User entered empty.	System	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User entered empty.	System	11 Nov 2020 16:50:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:14
User entered empty.	System	11 Nov 2020 16:50:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: FLUZONE [INFLUENZA VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:53:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:53:34
Data point term sent to Coder	System	11 Nov 2020 16:52:44
User entered 'Fluzone'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'Influenza prevention'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '0.5'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '4 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered '4 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 00:20:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User entered empty.	System	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User entered empty.	System	11 Nov 2020 16:51:59

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:17
User entered empty.	System	11 Nov 2020 16:51:59

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
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 08:17:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:17:49
Data point term sent to Coder	System	02 Apr 2021 22:08:41
User entered 'Aspirin'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Prevent coronary thrombosis'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '81'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '23 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:08:18

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:08:18

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:10:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:10:43
Data point term sent to Coder	System	02 Apr 2021 22:09:44
User entered 'Carvedilol'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Coronary artery disease'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '25'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '23 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:42
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:09:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:09:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
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)	02 Apr 2021 22:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:11:46
Data point term sent to Coder	System	02 Apr 2021 22:10:44
User entered 'Atorvastatin'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'coronary artery disease'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '80'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:10:13

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '23 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:10:13

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:10:13

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:17:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:17:47
Data point term sent to Coder	System	02 Apr 2021 22:16:48
User entered 'Clopidogrel'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Coronary artery disease'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '75'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:16:05

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:00:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:04:28
User closed query 'eSource says this is ongoing, please verify and update accordingly. Thank you.' (Site from CRA).		16 Apr 2021 23:04:16
Query 'eSource says this is ongoing, please verify and update accordingly. Thank you.' answered with 'correct as is. medication is still ongoing.' (Site from CRA).		16 Apr 2021 20:39:42
DataPoint Un-verified.		16 Apr 2021 20:39:01
User entered '23 Mar 2021' reason for change: Data Entry Error		16 Apr 2021 20:39:01
DataPoint Verified.		16 Apr 2021 19:58:36
User opened query 'eSource says this is ongoing, please verify and update accordingly. Thank you.' (Site from CRA).		16 Apr 2021 19:47:38
DataPoint Un-verified.		15 Apr 2021 23:38:56
Signature has been broken.		15 Apr 2021 23:38:56
User entered '11 Mar 2021' reason for change: New Information		15 Apr 2021 23:38:56
DataPoint Verified.		12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:23:56
	(b) (4)	
User entered '23 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:16:05

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:16:05

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
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)	02 Apr 2021 22:18:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 22:18:48
Data point term sent to Coder	System	02 Apr 2021 22:17:48
User entered 'Lisinopril'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Hypertension'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '30'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:17:22

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:06
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
User entered '11 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '23 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:08
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 23:37:46
User entered '30 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:17:22

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:17:22

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:30:07
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 Apr 2021 01:30:07
Data point term sent to Coder	System	15 Apr 2021 23:38:40
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 23:38:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:32:21
Data point term sent to Coder	System	02 Apr 2021 22:18:49
User entered 'Colchicine'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:38
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 23:38:27
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 23:38:27
User entered 'Subcutaneous emphysema upper thorax' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 23:38:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Subcutaneous air right upper thorax from pneumothorax'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0.6'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:18:37

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '25 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 22:18:37

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 22:18:37

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:59:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:59:22
Data point term sent to Coder Coding entries removed.	System Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:07:59 06 Apr 2021 00:07:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 00:05:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 00:05:07
Data point term sent to Coder User entered 'nitroglycerin'	System Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:58 06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'crescendo ANGINA' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:07:42
User entered 'Angina'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0.4'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'as needed (PRN)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Other (OTHER)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Sublingual'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '04 Mar 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:09:48
User entered '10 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered '0'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:56:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:23:56
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 00:03:41

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 00:03:41

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
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)	19 Apr 2021 08:03:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:03:24
Data point term sent to Coder	System	16 Apr 2021 20:37:18
Coding entries removed.	(b) (4), (b) (6)	16 Apr 2021 20:36:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
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)	16 Apr 2021 00:33:11
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 Apr 2021 00:33:11
Data point term sent to Coder	System	15 Apr 2021 22:21:30
User entered 'Aspirin'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:08:01
User closed query 'Please change the word "prevent" to Prophylaxis in eSource and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:07:49
Query 'Please change the word "prevent" to Prophylaxis in eSource and EDC. Thank you.' answered with 'updated, per query request ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 20:36:24
User entered 'Prophylaxis MYOCARDIAL INFARCTION' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Apr 2021 20:36:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User opened query 'Please change the word "prevent" to Prophylaxis in eSource and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:49:45
User entered 'Prevent myocardial infarction'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered '81'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered empty.	System	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered empty.	System	15 Apr 2021 22:21:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered empty.	System	15 Apr 2021 22:21:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:26:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
Data point term sent to Coder	System	15 Apr 2021 22:22:30
User entered 'Sodium Chloride flush for saline lock'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'Prophylaxis against line clotting off'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered '3'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:49
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User entered empty.	System	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User entered empty.	System	15 Apr 2021 22:22:03

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:30
User entered empty.	System	15 Apr 2021 22:22:03

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
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)	15 Apr 2021 23:30:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 23:30:08
Data point term sent to Coder	System	15 Apr 2021 23:29:34
User entered 'Lisinopril'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'Hypertension'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered '5'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered '01 Apr 2021'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 23:29:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 23:29:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:46:53
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 Apr 2021 14:46:53
Data point term sent to Coder	System	15 Apr 2021 23:30:34
User entered 'Lidocaine 1%'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'Prevent pain from right radial arterial line placement'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered '2'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User entered empty.	System	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User entered empty.	System	15 Apr 2021 23:30:21

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:34
User entered empty.	System	15 Apr 2021 23:30:21

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:25:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:25:52
Data point term sent to Coder	System	15 Apr 2021 23:32:35
User entered 'Heparin'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'Prevent clot during angiography'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered '2000'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'IU (IU)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:59
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User entered empty.	System	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User entered empty.	System	15 Apr 2021 23:32:00

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:36
User entered empty.	System	15 Apr 2021 23:32:00

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:09:40
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 Apr 2021 09:09:40
Data point term sent to Coder	System	15 Apr 2021 23:33:36
User entered 'Nitroglycerin'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'Prevent spasm of coronary arteries'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered '200'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'ug (ug)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User entered empty.	System	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User entered empty.	System	15 Apr 2021 23:32:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:40
User entered empty.	System	15 Apr 2021 23:32:47

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: PHENYLALKYLAMINE DERIVATIVES, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 08:24:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 08:24:18
Data point term sent to Coder	System	15 Apr 2021 23:34:37
User entered 'Verapamil'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'Prevent spasm of coronary arteries'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered '2.5'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:05
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User entered empty.	System	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User entered empty.	System	15 Apr 2021 23:33:57

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:43
User entered empty.	System	15 Apr 2021 23:33:57

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:45:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:45:55
Data point term sent to Coder	System	15 Apr 2021 23:35:38
User entered 'Versed'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'Conscious Sedation for angiography'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'l'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:34:50

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:11
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User entered empty.	System	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User entered empty.	System	15 Apr 2021 23:34:50

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:47
User entered empty.	System	15 Apr 2021 23:34:50

US3162072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:41:09
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 Apr 2021 01:41:09
Data point term sent to Coder	System	15 Apr 2021 23:36:39
User entered 'Fentanyl'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'Conscious sedation for angiography'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered '50'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'ug (ug)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:14
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User entered empty.	System	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User entered empty.	System	15 Apr 2021 23:35:47

**US3162072**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:29:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:49
User entered empty.	System	15 Apr 2021 23:35:47

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:29:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:37:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:33
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:13
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:59
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 17:14:32
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 04:45:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 04:45:39
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:39
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 04:45:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:45:36

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:37:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:33
User entered '12 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:43

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:37:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:33
User entered '5 vessel coronary bypass surgery'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:43

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:37:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:33
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:43

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:37:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Mar 2021 18:52:43

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:50
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:04:37

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:50
User entered 'EKG ( Emergency Room)'	(b) (4), (b) (6)	15 Apr 2021 22:04:37

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:04:37

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:50
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:04:37

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:52
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:05:05

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:52
User entered 'EKG (Emergency Room)'	(b) (4), (b) (6)	15 Apr 2021 22:05:05

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:52
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:05:05

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:05:05

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:55
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:05:24

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:55
User entered 'Stress ECHO'	(b) (4), (b) (6)	15 Apr 2021 22:05:24

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:55
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:05:24

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:29:54**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:05:24

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:56
User entered '16 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:05:51

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:56
User entered 'Bilateral Chest Tube insertion'	(b) (4), (b) (6)	15 Apr 2021 22:05:51

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:56
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:05:51

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:29:54**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:05:51

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:59
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:08:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:59
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:08:04

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:59
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:08:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:59
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:08:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:00
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:08:29

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:00
User entered 'ECG (Different Hospital)'	(b) (4), (b) (6)	15 Apr 2021 22:08:29

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:00
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:08:29

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:00
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:08:29

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:04
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:08:54

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:04
User entered 'ECG'	(b) (4), (b) (6)	15 Apr 2021 22:08:54

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:04
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:08:54

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:04
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:08:54

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:05
User entered '13 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:09:13

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:05
User entered 'ECG'	(b) (4), (b) (6)	15 Apr 2021 22:09:13

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:05
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:09:13

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:05
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:09:13

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:08
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:09:39

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:08
User entered 'Placement of arterial line'	(b) (4), (b) (6)	15 Apr 2021 22:09:39

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:08
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 22:09:39

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:08
User entered 'Pre-Operative procedure'	(b) (4), (b) (6)	15 Apr 2021 22:09:39

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:09
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:10:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:09
User entered 'Placement of central line'	(b) (4), (b) (6)	15 Apr 2021 22:10:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 22:10:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:09
User entered 'Pre-operative procedure'	(b) (4), (b) (6)	15 Apr 2021 22:10:04

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:12
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:10:35

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:12
User entered 'Spirometry'	(b) (4), (b) (6)	15 Apr 2021 22:10:35

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 22:10:35

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:12
User entered 'pre-operative procedure'	(b) (4), (b) (6)	15 Apr 2021 22:10:35

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:13
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:11:08

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:13
User entered 'Trans-esophageal ECHO'	(b) (4), (b) (6)	15 Apr 2021 22:11:08

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:13
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 22:11:08

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:13
User entered 'Intra-operative procedure'	(b) (4), (b) (6)	15 Apr 2021 22:11:08

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:18
User entered '14 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:11:38

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:18
User entered 'Trans-thoracic ECHO'	(b) (4), (b) (6)	15 Apr 2021 22:11:38

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 22:11:38

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:18
User entered 'Post-operative monitoring'	(b) (4), (b) (6)	15 Apr 2021 22:11:38

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:19
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:12:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:19
User entered 'Chest-X-ray (different hospital)'	(b) (4), (b) (6)	15 Apr 2021 22:12:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:12:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:19
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:12:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:23
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:12:30

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:23
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:12:30

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:23
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:12:30

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:23
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:12:30

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:24
User entered '13 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:12:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:24
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:12:55

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (17)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:24
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:12:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:24
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:12:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:28
User entered '14 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:13:18

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:28
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:13:18

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:28
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:13:18

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:28
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:13:18

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (19)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:30
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:13:32

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:30
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:13:32

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (19)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:13:32

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:30
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:13:32

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:36
User entered '16 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:13:52

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:36
User entered 'Chest X-ray (3)'	(b) (4), (b) (6)	15 Apr 2021 22:13:52

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (20)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:36
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 22:14:24
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:13:52

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:36
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:13:52

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (21)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:37
User entered '17 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:14:16

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:37
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:14:16

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (21)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:14:16

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:37
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:14:16

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (22)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:40
User entered '18 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:14:41

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:40
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:14:41

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (22)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:40
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:14:41

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:40
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:14:41

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (23)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:42
User entered '19 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:14:58

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:42
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:14:58

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:42
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:14:58

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:42
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:14:58

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:44
User entered '20 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:15:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:44
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:15:11

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (24)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:44
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:15:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:44
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:15:11

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:45
User entered '21 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:15:27

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:45
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:15:27

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (25)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:45
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:15:27

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:45
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:15:27

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (26)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:51
User entered '22 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:15:48

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:51
User entered 'Chest X-ray (2)'	(b) (4), (b) (6)	15 Apr 2021 22:15:48

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:51
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:15:48

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:51
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:15:48

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (27)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:52
User entered '23 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:16:01

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:52
User entered 'Chest X-ray'	(b) (4), (b) (6)	15 Apr 2021 22:16:01

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:52
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:16:01

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:52
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:16:01

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	15 Apr 2021 22:16:32
User entered '20 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 22:16:32
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	15 Apr 2021 22:16:22
User entered '20 Mar 2020'	(b) (4), (b) (6)	15 Apr 2021 22:16:22

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered 'Brain MRI'	(b) (4), (b) (6)	15 Apr 2021 22:16:22

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (28)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:16:22

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:16:22

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:16:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered 'Coronary angiography'	(b) (4), (b) (6)	15 Apr 2021 22:16:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 22:16:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:07:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:16:55

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:01
User entered '11 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 22:17:20

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (30)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:01
User entered 'Placement of arterial line for angiography'	(b) (4), (b) (6)	15 Apr 2021 22:17:20

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 15:29:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:01
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	15 Apr 2021 22:17:20

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:01
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 22:17:20

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:02
User entered '12 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 18:15:39

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (31)**

**Generated On: 09 Jun 2021 15:29:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:02
User entered 'Placement of Foley catheter'	(b) (4), (b) (6)	16 Apr 2021 18:15:39

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (31)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:02
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:15:39

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:02
User entered 'Pre-operative procedure'	(b) (4), (b) (6)	16 Apr 2021 18:15:39

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 15:29:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:22
User entered '12 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 18:16:02

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:06:23
User closed query 'Per source procedure is recorded as 'Right Lower Extremity Endoscopic Vein Harvest'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:06:11
Query 'Per source procedure is recorded as 'Right Lower Extremity Endoscopic Vein Harvest'. Please reconcile. ' answered with 'data entry error. Con procedure updated. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:34:35
User entered 'RIGHT LOWER EXTREMITY ENDOSCOPIC Vein Harvest' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 20:34:05
User opened query 'Per source procedure is recorded as 'Right Lower Extremity Endoscopic Vein Harvest'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:06:19
User entered 'Right lower extremity endoscopic'	(b) (4), (b) (6)	16 Apr 2021 18:16:02

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (32)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:24
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	16 Apr 2021 18:16:02

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:26
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 18:16:02

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (33)**

**Generated On: 09 Jun 2021 15:29:54**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:05
User entered '12 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 18:16:38

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 15:29:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:05
User entered 'Endotracheal intubation'	(b) (4), (b) (6)	16 Apr 2021 18:16:38

**US3162072**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (33)**

**Generated On: 09 Jun 2021 15:29:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:05
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 18:16:38

US3162072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 15:29:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:08:05
User entered 'Pre-operative procedure for anesthesia'	(b) (4), (b) (6)	16 Apr 2021 18:16:38

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'USA-US074-2021-MRNA-1273-P301000020'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Judith'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Kirstein'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'BANNING'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'CA'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '92220'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered 'US'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:01:49
User entered '2'	System	16 Apr 2021 15:05:31
User entered '1'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'USA-US074-2021-MRNA-1273-P301000020'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Judith'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Kirstein'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'BANNING'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'CA'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '92220'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered 'US'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:01:49
User entered '2'	System	16 Apr 2021 15:05:31
User entered '1'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered '25/Mar/2021 09:27'	System	25 Mar 2021 14:28:02

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:29:54

**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)	24 Apr 2021 23:00:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'USA-US074-2021-MRNA-1273-P301000020'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Judith'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Kirstein'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'BANNING'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'CA'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '92220'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered 'US'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:01:49
User entered '2'	System	16 Apr 2021 15:05:31
User entered '1'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:55:59
User entered '16/Apr/2021 10:05'	System	16 Apr 2021 15:05:31

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:29:54

**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)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:55:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:01:37
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 15:05:31

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'USA-US074-2021-MRNA-1273-P301000020'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Yes (Y)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'No (N)'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Judith'	System	25 Mar 2021 14:26:28

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'Kirstein'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'BANNING'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered 'CA'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:27:51
User entered '92220'	System	25 Mar 2021 14:26:28

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:51:30
User entered 'US'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:01:49
User entered '2'	System	16 Apr 2021 15:05:31
User entered '1'	System	25 Mar 2021 14:28:02

**US3162072**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:29:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:56:01
User entered '19/Apr/2021 09:01'	System	19 Apr 2021 13:01:49

US3162072

Folder: SAE USA-US074-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:29:54

**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)	24 Apr 2021 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:56:01
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:01:49