

US3162068 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:28:48

All time stamps listed in this document are displayed in GMT

US3162068

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Participant ID

US3162068

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

US3162068

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3162068

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 01:02:05

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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

US3162068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3162068

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3162068

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Condition	TENDINITIS LEFT SHOULDER
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3162068

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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>)	11:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:30
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	185 lb
BMI (<i>xxx.x</i>)	26.60024 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:02:05

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

What was the participant's randomization number? 185046

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Height	ND - Not Done
Weight	ND - Not Done

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

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)	11:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:30
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Height	ND - Not Done
Weight	ND - Not Done
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)	6 AUG 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 13:19
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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.

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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) 12:43 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 12:43

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 6 AUG 2020

Collection time (00:00-23:59) 12:38 (24 HR)

Collection date and time (derived) 6 AUG 2020 12:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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	12:40	6 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

US3162068

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:18

PC Open Date & Time

06 AUG 2020 13:03

PC Close Date & Time

06 AUG 2020 15:33

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	06 AUG 2020 17:20
PC Open Date & Time	06 AUG 2020 16:28
PC Close Date & Time	07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 AUG 2020 12:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 13:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 15:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

97.7 °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

10 AUG 2020 13:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 13:19

PC Open Date & Time

06 AUG 2020 13:03

PC Close Date & Time

06 AUG 2020 15:33

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 17:21

PC Open Date & Time

06 AUG 2020 16:28

PC Close Date & Time

07 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 12:24

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 13:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 15:21

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 13:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 12:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 12:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 13:21
PC Open Date & Time	06 AUG 2020 13:03
PC Close Date & Time	06 AUG 2020 15:33

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 17:21
PC Open Date & Time	06 AUG 2020 16:28
PC Close Date & Time	07 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

50 of 3072

EAB) (1725)

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:24
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

52 of 3072

EAB) (1725)

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 13:08
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 ☒

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 15:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 ☒

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:19
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

58 of 3072

EAB) (1725)

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

60 of 3072

EAB) (1725)

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3162068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:08
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:06
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:30

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

US3162068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 04 SEP 2020

Collection time (00:00-23:59) 13:25 (24 HR)

Collection date and time (derived) 04 SEP 2020 13:25

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	04 SEP 2020 13:30
Nasopharyngeal Swab 2	No		

US3162068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

97.6 °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

04 SEP 2020 15:01

PC Open Date & Time

04 SEP 2020 14:50

PC Close Date & Time

04 SEP 2020 17:20

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 97.6 °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	04 SEP 2020 18:50
PC Open Date & Time	04 SEP 2020 18:15
PC Close Date & Time	05 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

98.3 °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

07 SEP 2020 09:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

97.9 °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

09 SEP 2020 12:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

04 SEP 2020 15:01

PC Open Date & Time

04 SEP 2020 14:50

PC Close Date & Time

04 SEP 2020 17:20

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

04 SEP 2020 18:50

PC Open Date & Time

04 SEP 2020 18:15

PC Close Date & Time

05 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

05 SEP 2020 12:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

07 SEP 2020 09:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

07 SEP 2020 12:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

09 SEP 2020 12:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

10 SEP 2020 12:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:01
PC Open Date & Time	04 SEP 2020 14:50
PC Close Date & Time	04 SEP 2020 17:20

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 18:50
PC Open Date & Time	04 SEP 2020 18:15
PC Close Date & Time	05 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:34
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 09:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:04
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:07
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3162068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:16 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:16
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	57 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

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.

US3162068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	2 OCT 2020 10:32

US3162068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:06

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 10:28:22
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 12:00:46

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 20:47:45

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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	03 NOV 2020 21:01:24
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 08:05:56

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

17 NOV 2020 11:36:14

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

01 DEC 2020 13:49:46

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

07 DEC 2020 12:00:25

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 18:59:59
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

19 DEC 2020 07:30:18

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 07:35:59

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 07:59:36
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 07:56:15

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 08:23:53

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 JAN 2021 08:05:14
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

30 JAN 2021 07:29:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 07:35:13

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:50:43

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 FEB 2021 07:52:21
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

27 FEB 2021 08:02:00

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

06 MAR 2021 10:28:27

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:43:19

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 08:31:54

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 08:07:18

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 12:16:45

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 APR 2021 05:07:19
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

18 APR 2021 08:51:51

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

24 APR 2021 07:42:47

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 08:32:55

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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="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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 <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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 418

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

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

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

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

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 <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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

Patient Cloud Open Date & Time	20 NOV 2021 00:01
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Patient Cloud Close Date & Time	24 NOV 2021 23:59
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US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 <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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

Patient Cloud Open Date & Time	23 APR 2022 00:01
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Patient Cloud Close Date & Time	27 APR 2022 23:59
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US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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="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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 <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"/>

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:28:48

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		27 FEB 2021 08:02:14

US3162068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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) _____

US3162068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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.

US3162068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

Collection date (dd MMM yyyy)	17 MAR 2021
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Collection time (00:00-23:59)	10:39 (24 HR)
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Collection date and time (derived)	17 MAR 2021 10:39
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US3162068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162068

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:28:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3162068

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

Visit date (dd MMM yyyy)	20 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3162068

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3162068

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Height	70 in
Weight	185 lb
BMI (xxx.x)	26.60024

US3162068

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Height	70 in
Weight	185 lb
BMI (xxx.x)	26.60024
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)	20 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 11:25
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Height	70 in
Weight	185 lb
BMI (xxx.x)	26.60024
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)	20 JAN 2021
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 12:33
Temperature (xxx.x)	99.2 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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.

US3162068

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

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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) 20 JAN 2021

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 11:58

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

US3162068

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 20 JAN 2021

Collection time (00:00-23:59) 11:30 (24 HR)

Collection date and time (derived) 20 JAN 2021 11:30

US3162068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00 - 23:59)	11:35
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Collection Date and Time (derived)	20 JAN 2021 11:35
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US3162068

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3162068

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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)	18 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 11:20
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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)	18 FEB 2021
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 12:25
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3162068

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3162068

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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) 18 FEB 2021

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 11:50

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

US3162068

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162068

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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) _____

US3162068

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

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.

US3162068

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3162068

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID	
Adverse event	MID ABDOMINAL PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID

Adverse event

RIGHT GREAT TOE ULCER

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)

1 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)

7 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 ☐

Number of Days in ICU

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US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID	USA-US074-2021-MRNA-1273-P30 1000021
Adverse event	OSTEOMYELITIS RIGHT GREAT TOE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 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)	7 APR 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)	7 APR 2021
Hospital Discharge Date (dd MMM yyyy)	10 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

SUBJECT DEVELOPED ULCER
ON PLANTAR SURFACE OF
RIGHT GREAT TOE AND
CELLULITIS, WHICH FAILED
OUTPATIENT MANAGEMENT
AND CAUSED OSTEOMYELITIS
WHICH LED TO THE TOE BEING
AMPUTATED ON 07APR2021. IN
THE HOSPITAL, SUBJECT WAS
TREATED WITH IV
VANCOMYCIN, CEFTRIAXONE
AND METRONIDAZOLE. HE
WAS SENT HOME ON IV
CEFTRIAXONE AND ORAL
METRONIDAZOLE TO
COMPLETE A 14 DAY COURSE.
PATHOLOGY OF HIS
AMPUTATED TOE SHOWED
OSTEOMYELITIS BUT HIS
METATARSAL BONE BIOPSY
DONE 07APR2021 SHOWED NO
INFECTION (REPORTED
13APR2021.) DURING THE
HOSPITAL STAY, HE
EXPERIENCED CONSTIPATION,
INTERMITTENT ELEVATIONS
OF HIS BLOOD PRESSURE
BETWEEN 08APR AND 10APR,
MILD NONSPECIFIC ANEMIA,
WITH HEMOGLOBIN 11.7 G/DL
(NORMAL 14-18) AND
HEMATOCRIT 34.5 G/DL
(NORMAL 42-52), ELEVATIONS
OF ERYTHROCYTE
SEDIMENTATION RATE (46
MM/HOUR WITH NORMAL
BEING 0-20) AND C-REACTIVE
PROTEIN (64 MG/L, WITH
NORMAL BEING <7.4) , AND
TRANSIENT ELEVATED BLOOD
UREA NITROGEN 27 MG/DL ON
07APR, DECLINING TO 18 ON
09APR (NORMAL <18).

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID	
Adverse event	CONSTIPATION
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)	9 APR 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)	11 APR 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 15:59:33

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID

Adverse event

TRANSIENT ELEVATION OF
BLOOD UREA NITROGEN

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)

7 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 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 ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID

Adverse event

MILD NON-SPECIFIC ANEMIA

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 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID

Adverse event

INTERMITTENT ELEVATION OF
BLOOD PRESSURE

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 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 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 ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

AEID	
Adverse event	CELLULITIS RIGHT GREAT TOE
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)	22 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)	22 APR 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 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	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 15:59:33

Generated On: 09 Jun 2021 15:28:48

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

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 01:02:05

Generated On: 09 Jun 2021 15:28:48

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication VOLTAREN GEL

Prophylaxis Yes ☐
No ☒

Indication TENDINITIS LEFT SHOULDER

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication BACTRIM DS
(SULFAMETHOXAZOLE/TRIMET
HOPRIM)

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	29 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)	7 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication INFLUENZA VACCINE

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 CC

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication FLOVENT

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication FLUNISOLIDE .025% NASAL SPRAY

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 checked="" 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)	07 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	22 APR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)		7 APR 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 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 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MIRALAX (POLYETHYLENE GLYCOL)

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication SENOKOT (SENNOSIDES)

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 17.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS RIGHT GREAT
TOE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="radio"/>
	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 checked="" 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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

Dose per administration 1500

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

EVERY 12 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	10 APR 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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MARCAINE 0.5%

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS AGAINST PAIN
FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS AGAINST PAIN
FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication NORMAL SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication PREVENT CLOT IN
INTRAVENOUS LINE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication 5% DEXTROSE/0.45% SALINE IV
FLUID

Prophylaxis Yes ☒
No ☐

Indication PREVENT DEHYDRATION

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

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)		9 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication PREVENT GASTRIC
HYPERACIDITY

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication PREVENT THROMBOSIS

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication LACTATE RINGER'S IV
SOLUTION

Prophylaxis Yes ☒
No ☐

Indication PREVENT DEHYDRATION

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication PREVENT INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 APR 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"/>

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 checked="" 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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
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"/>

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM RIGHT GREAT TOE
AMPUTATION

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 APR 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"/>

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication LACTATED RINGERS IV
SOLUTION

Prophylaxis Yes ☒
No ☐

Indication PREVENT DEHYDRATION
DURING SURGERY

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

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 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"/>

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication ANESTHESIA FOR RIGHT
GREAT TOE AMPUTATION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication ANESTHESIA FOR RIGHT
GREAT TOE AMPUTATION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication PROPOFOL DRIP

Prophylaxis Yes ☐
No ☒

Indication ANESTHESIA FOR RIGHT
GREAT TOE AMPUTATION

Dose per administration 300

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

CONTINUOUS DURING
OPERATION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="radio"/>
	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 checked="" 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)		7 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication PREVENT NAUSEA DURING SURGERY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="radio"/>
	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 checked="" 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)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication LIDOCAINE

Prophylaxis Yes ☒
No ☐

Indication PREVENT ARRHYTHMIAS
DURING SURGERY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intraocular	<input type="radio"/>
	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 checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	7 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROTECTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS RIGHT GREAT TOE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 22:27:08

Generated On: 09 Jun 2021 15:28:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Apr 2021 22:59:55

Generated On: 09 Jun 2021 15:28:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 APR 2021	RIGHT GREAT TOE AMPUTATION	Adverse Event	
7 APR 2021	RIGHT FIRST METATARSAL BONE BIOPSY	Adverse Event	

US3162068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:28:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3162068

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:28:48

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 ☐

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5

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Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 10:52
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

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5
Date of submission (Pre-filled from custom function)	13/APR/2021 08:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5
Date of submission (Pre-filled from custom function)	21/APR/2021 13:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5
Date of submission (Pre-filled from custom function)	23/APR/2021 09:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 15:29:31

Generated On: 09 Jun 2021 15:28:48

SAEID	USA-US074-2021-MRNA-1273-P301000021
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)	5
Date of submission (Pre-filled from custom function)	30/APR/2021 06:28
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

US3162068 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162068

Form: Participant Creation

Generated On: 09 Jun 2021 15:28:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'US3162068'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 18:59:16

US3162068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:09

US3162068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 18:59:17

US3162068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:09

US3162068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'SCRN'	System	07 Aug 2020 03:56:09

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 18:59:17

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '66'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'YEARS'	System	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '66'	System	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Male (M)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:27

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Aug 2020'	System	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2020'	System	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:34

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 18:59:17

US3162068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'I'	System	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:28:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:33

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 03:58:04
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 03:58:04
Data point term sent to Coder	System	07 Aug 2020 03:57:27
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2000'	System	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2000'	System	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	07 Aug 2020 03:56:46

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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)	13 Sep 2020 23:32:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 23:32:37
Data point term sent to Coder	System	13 Sep 2020 23:31:35
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	13 Sep 2020 23:30:56
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	13 Sep 2020 23:30:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 03:58:04
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 03:58:04
Data point term sent to Coder	System	07 Aug 2020 03:57:27
User entered 'hypercholesterolemia'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2000'	System	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2000'	System	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	07 Aug 2020 03:57:03

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Shoulder tendinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:06:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:06:24
Data point term sent to Coder	System	21 Jan 2021 02:59:03
User entered 'tendinitis left shoulder'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'un Jun 2020'	Jessica Fisher (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jessica Fisher (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jessica Fisher (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jessica Fisher (b) (4)	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jun 2020'	System	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2020'	System	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	21 Jan 2021 02:58:38

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Glucose intolerance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:15:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:15:35
Data point term sent to Coder	System	17 Apr 2021 00:14:22
User entered 'Glucose Intolerance'	(b) (4), (b) (6)	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:14:16

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:14:16

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2014'	System	17 Apr 2021 00:14:16

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2014'	System	17 Apr 2021 00:14:16

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:14:16

US3162068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:16:35
Data point term sent to Coder	System	17 Apr 2021 00:15:22
User entered 'Mild Asthma'	(b) (4), (b) (6)	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:14:40

US3162068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2014'	System	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2014'	System	17 Apr 2021 00:14:40

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:14:40

US3162068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:14:40

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:16:35
Data point term sent to Coder	System	17 Apr 2021 00:15:22
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	17 Apr 2021 00:15:14

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:15:14

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2014'	System	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2014'	System	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:15:14

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:17:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:17:35
Data point term sent to Coder	System	17 Apr 2021 00:16:23
User entered 'Environmental Allergies'	(b) (4), (b) (6)	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 1990'	(b) (4), (b) (6)	17 Apr 2021 00:15:41

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:15:41

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 1990'	System	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '1990'	System	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:15:41

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:40:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:40:05
Data point term sent to Coder	System	17 Apr 2021 00:16:23
User entered 'Sensory Neuropathy bilateral great toes'	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 1988'	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 1988'	System	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '1988'	System	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:16:10

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:18:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:18:35
Data point term sent to Coder	System	17 Apr 2021 00:17:23
User entered 'Chronic Low back Pain'	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'Jan 2014'	System	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '2014'	System	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered empty.	System	17 Apr 2021 00:16:31

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:30'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered '6 Aug 2020 11:30'	System	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '70' in	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12
DataPoint set to visible.	System	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '185' lb	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12
DataPoint set to visible.	System	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
Amendment Manager: User entered '26.60024'	System	16 Sep 2020 23:46:04
User entered '26.6'	System	07 Aug 2020 03:58:12
DataPoint set to visible.	System	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'kg/m2'	System	07 Aug 2020 03:58:12
DataPoint set to visible.	System	06 Aug 2020 19:49:40

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 17:49:18
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 02:03:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:30:37
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 17:11:31
User entered '97.5' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:30:37
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:30:37
User entered '80'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'bpm'	System	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:30:37
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'breaths/min'	System	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:30:37
User entered '125'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'mmHg'	System	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 03:30:37
User entered '78'	(b) (4)	
	Jared Bradshaw (b) (4)	07 Aug 2020 03:58:12
	(b) (4)	

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User entered 'mmHg'	System	07 Aug 2020 03:58:12

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14

US3162068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14

US3162068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:23

US3162068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 20:17:04
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:23

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:43

US3162068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:57

US3162068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered '6 Aug 2020'	Jared Bradshaw (b) (4)	07 Aug 2020 03:58:57
	(b) (4)	

US3162068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:58:57

US3162068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'VISIT1'	System	07 Aug 2020 03:58:57

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:14:21

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:38:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:38:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 19:14:21
User entered '185046' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:14:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:14:21

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:59:05

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:59:05

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:59:05

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:59:05

US3162068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 03:59:05

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:30'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '6 Aug 2020 11:30'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '97.5' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '80'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'bpm'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'breaths/min'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '125'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'mmHg'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '78'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'mmHg'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 17:23:03
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 04:00:42
User entered '13:19'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '6 Aug 2020 13:19'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '97.5' F	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '62'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'bpm'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'breaths/min'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '125'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'mmHg'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '82'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'mmHg'	System	07 Aug 2020 04:00:42

US3162068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:49

US3162068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:49

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '12:43'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '6 Aug 2020 12:43'	System	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'ONCE'	System	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 19:50:05

US3162068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:59

US3162068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:59

US3162068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '12:38'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:00:59

US3162068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '6 Aug 2020 12:38'	System	07 Aug 2020 04:00:59

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '6 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '12:40'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '6 Aug 2020 12:40'	System	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered empty.	System	07 Aug 2020 04:01:14

US3162068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:23

US3162068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	07 Aug 2020 04:01:23

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:17:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'aed3159d-1198-43f3-b134-ef51c6891b02' User entered 'Yes (Y)'	System	06 Aug 2020 20:18:18
	System	06 Aug 2020 20:18:18

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:17:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'aed3159d-1198-43f3-b134-ef51c6891b02' User entered '97.5'	System	06 Aug 2020 20:18:18
	System	06 Aug 2020 20:18:18

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:17:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'aed3159d-1198-43f3-b134-ef51c6891b02'	System	06 Aug 2020 20:18:18
User entered 'No (N)'	System	06 Aug 2020 20:18:18

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:18:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'aed3159d-1198-43f3-b134-ef51c6891b02' User entered '06 Aug 2020 13:18'	System	06 Aug 2020 20:18:18
	System	06 Aug 2020 20:18:18

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 13:03'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 15:33'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '08d1f688-ff4a-4258-a372-86004f20d2c8'	System	07 Aug 2020 00:20:35
User entered 'Yes (Y)'	System	07 Aug 2020 00:20:35

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '08d1f688-ff4a-4258-a372-86004f20d2c8'	System	07 Aug 2020 00:20:35
User entered '98.5'	System	07 Aug 2020 00:20:35

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:25', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '08d1f688-ff4a-4258-a372-86004f20d2c8'	System	07 Aug 2020 00:20:35
User entered 'No (N)'	System	07 Aug 2020 00:20:35

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:30', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '08d1f688-ff4a-4258-a372-86004f20d2c8'	System	07 Aug 2020 00:20:35
User entered '06 Aug 2020 17:20'	System	07 Aug 2020 00:20:35

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 16:28'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 2'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:23:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '2cc5d189-8b4c-4c31-8062-08294d7530c0' User entered 'Yes (Y)'	System	07 Aug 2020 19:23:58
	System	07 Aug 2020 19:23:58

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:23:47', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '2cc5d189-8b4c-4c31-8062-08294d7530c0' User entered '97.8'	System	07 Aug 2020 19:23:58
	System	07 Aug 2020 19:23:58

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:23:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '2cc5d189-8b4c-4c31-8062-08294d7530c0'	System	07 Aug 2020 19:23:58
User entered 'No (N)'	System	07 Aug 2020 19:23:58

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:23:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '2cc5d189-8b4c-4c31-8062-08294d7530c0' User entered '07 Aug 2020 12:23'	System	07 Aug 2020 19:23:58
	System	07 Aug 2020 19:23:58

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 3'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dec7d089-fd32-4a7f-8697-8707077fa4b7'	System	08 Aug 2020 20:08:21
User entered 'Yes (Y)'	System	08 Aug 2020 20:08:21

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:11', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dec7d089-fd32-4a7f-8697-8707077fa4b7' User entered '98.2'	System	08 Aug 2020 20:08:21
	System	08 Aug 2020 20:08:21

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dec7d089-fd32-4a7f-8697-8707077fa4b7'	System	08 Aug 2020 20:08:21
User entered 'No (N)'	System	08 Aug 2020 20:08:21

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dec7d089-fd32-4a7f-8697-8707077fa4b7'	System	08 Aug 2020 20:08:21
User entered '08 Aug 2020 13:08'	System	08 Aug 2020 20:08:21

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 4'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:20:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '662d3b45-57a4-497f-a414-e8fbe081b885'	System	09 Aug 2020 22:21:00
User entered 'Yes (Y)'	System	09 Aug 2020 22:21:00

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:20:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '662d3b45-57a4-497f-a414-e8fbe081b885' User entered '98.0'	System	09 Aug 2020 22:21:00
	System	09 Aug 2020 22:21:00

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:20:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '662d3b45-57a4-497f-a414-e8fbe081b885'	System	09 Aug 2020 22:21:00
User entered 'No (N)'	System	09 Aug 2020 22:21:00

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:20:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '662d3b45-57a4-497f-a414-e8fbe081b885'	System	09 Aug 2020 22:21:00
User entered '09 Aug 2020 15:20'	System	09 Aug 2020 22:21:00

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 5'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:17:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a9577ecc-8b06-47dd-a8f8-a3d7a7c01dbc' User entered 'Yes (Y)'	System	10 Aug 2020 20:18:39
	System	10 Aug 2020 20:18:39

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a9577ecc-8b06-47dd-a8f8-a3d7a7c01dbc' User entered '97.7'	System	10 Aug 2020 20:18:39
	System	10 Aug 2020 20:18:39

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:28', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a9577ecc-8b06-47dd-a8f8-a3d7a7c01dbc'	System	10 Aug 2020 20:18:39
User entered 'No (N)'	System	10 Aug 2020 20:18:39

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a9577ecc-8b06-47dd-a8f8-a3d7a7c01dbc' User entered '10 Aug 2020 13:18'	System	10 Aug 2020 20:18:39
	System	10 Aug 2020 20:18:39

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 6'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e8dbc14-3a96-4958-a113-28c024503146' User entered 'Yes (Y)'	System	11 Aug 2020 19:15:37
	System	11 Aug 2020 19:15:37

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e8dbc14-3a96-4958-a113-28c024503146' User entered '98.4'	System	11 Aug 2020 19:15:37
	System	11 Aug 2020 19:15:37

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:30', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e8dbc14-3a96-4958-a113-28c024503146'	System	11 Aug 2020 19:15:37
User entered 'No (N)'	System	11 Aug 2020 19:15:37

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:33', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e8dbc14-3a96-4958-a113-28c024503146' User entered '11 Aug 2020 12:15'	System	11 Aug 2020 19:15:37
	System	11 Aug 2020 19:15:37

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 7'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0635fefa-9fef-4864-94ec-1a34f494d2de' User entered 'Yes (Y)'	System	12 Aug 2020 19:00:40
	System	12 Aug 2020 19:00:40

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0635fefa-9fef-4864-94ec-1a34f494d2de' User entered '98.2'	System	12 Aug 2020 19:00:40
	System	12 Aug 2020 19:00:40

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0635fefa-9fef-4864-94ec-1a34f494d2de'	System	12 Aug 2020 19:00:40
User entered 'No (N)'	System	12 Aug 2020 19:00:40

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0635fefa-9fef-4864-94ec-1a34f494d2de'	System	12 Aug 2020 19:00:40
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 19:00:40

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:18:37', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '396735c1-ebd4-4526-95f9-792a7c166215'	System	06 Aug 2020 20:19:16
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 20:19:16

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:18:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '396735c1-ebd4-4526-95f9-792a7c166215' User entered 'No (N)'	System	06 Aug 2020 20:19:16
	System	06 Aug 2020 20:19:16

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:19:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '396735c1-ebd4-4526-95f9-792a7c166215' User entered 'No (N)'	System	06 Aug 2020 20:19:16
	System	06 Aug 2020 20:19:16

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:19:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '396735c1-ebd4-4526-95f9-792a7c166215' User entered 'None (1)'	System	06 Aug 2020 20:19:16
	System	06 Aug 2020 20:19:16

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:19:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '396735c1-ebd4-4526-95f9-792a7c166215' User entered '06 Aug 2020 13:19'	System	06 Aug 2020 20:19:16
	System	06 Aug 2020 20:19:16

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 13:03'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 15:33'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4981fb7d-2d36-41d6-9a97-8030a8a842d4' User entered 'None (1)'	System	07 Aug 2020 00:21:08
	System	07 Aug 2020 00:21:08

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4981fb7d-2d36-41d6-9a97-8030a8a842d4'	System	07 Aug 2020 00:21:08
User entered 'No (N)'	System	07 Aug 2020 00:21:08

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4981fb7d-2d36-41d6-9a97-8030a8a842d4' User entered 'No (N)'	System	07 Aug 2020 00:21:08
	System	07 Aug 2020 00:21:08

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:20:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4981fb7d-2d36-41d6-9a97-8030a8a842d4'	System	07 Aug 2020 00:21:08
User entered 'None (1)'	System	07 Aug 2020 00:21:08

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4981fb7d-2d36-41d6-9a97-8030a8a842d4' User entered '06 Aug 2020 17:21'	System	07 Aug 2020 00:21:08
	System	07 Aug 2020 00:21:08

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 16:28'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 2'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3b97138d-10bd-4034-ac72-e76c64335e9d'	System	07 Aug 2020 19:24:13
User entered 'None (1)'	System	07 Aug 2020 19:24:13

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3b97138d-10bd-4034-ac72-e76c64335e9d'	System	07 Aug 2020 19:24:13
User entered 'No (N)'	System	07 Aug 2020 19:24:13

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:05', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3b97138d-10bd-4034-ac72-e76c64335e9d' User entered 'No (N)'	System	07 Aug 2020 19:24:13
	System	07 Aug 2020 19:24:13

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:08', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3b97138d-10bd-4034-ac72-e76c64335e9d'	System	07 Aug 2020 19:24:13
User entered 'None (1)'	System	07 Aug 2020 19:24:13

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:11', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3b97138d-10bd-4034-ac72-e76c64335e9d' User entered '07 Aug 2020 12:24'	System	07 Aug 2020 19:24:13
	System	07 Aug 2020 19:24:13

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 3'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0eb21929-ee00-4dce-a56b-dde584a33aac'	System	08 Aug 2020 20:08:36
User entered 'None (1)'	System	08 Aug 2020 20:08:36

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0eb21929-ee00-4dce-a56b-dde584a33aac' User entered 'No (N)'	System	08 Aug 2020 20:08:36
	System	08 Aug 2020 20:08:36

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0eb21929-ee00-4dce-a56b-dde584a33aac'	System	08 Aug 2020 20:08:36
User entered 'No (N)'	System	08 Aug 2020 20:08:36

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0eb21929-ee00-4dce-a56b-dde584a33aac'	System	08 Aug 2020 20:08:36
User entered 'None (1)'	System	08 Aug 2020 20:08:36

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:34', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0eb21929-ee00-4dce-a56b-dde584a33aac' User entered '08 Aug 2020 13:08'	System	08 Aug 2020 20:08:36
	System	08 Aug 2020 20:08:36

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 4'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:20:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '993ee7c0-edca-4e8a-a0d7-ee0f65c6da34'	System	09 Aug 2020 22:21:11
User entered 'None (1)'	System	09 Aug 2020 22:21:11

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:02', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '993ee7c0-edca-4e8a-a0d7-ee0f65c6da34' User entered 'No (N)'	System	09 Aug 2020 22:21:11
	System	09 Aug 2020 22:21:11

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '993ee7c0-edca-4e8a-a0d7-ee0f65c6da34' User entered 'No (N)'	System	09 Aug 2020 22:21:11
	System	09 Aug 2020 22:21:11

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '993ee7c0-edca-4e8a-a0d7-ee0f65c6da34'	System	09 Aug 2020 22:21:11
User entered 'None (1)'	System	09 Aug 2020 22:21:11

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '993ee7c0-edca-4e8a-a0d7-ee0f65c6da34' User entered '09 Aug 2020 15:21'	System	09 Aug 2020 22:21:11
	System	09 Aug 2020 22:21:11

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 5'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0b23d64b-63df-4060-b2a6-150321514216'	System	10 Aug 2020 20:18:49
User entered 'None (1)'	System	10 Aug 2020 20:18:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0b23d64b-63df-4060-b2a6-150321514216' User entered 'No (N)'	System	10 Aug 2020 20:18:49
	System	10 Aug 2020 20:18:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0b23d64b-63df-4060-b2a6-150321514216' User entered 'No (N)'	System	10 Aug 2020 20:18:49
	System	10 Aug 2020 20:18:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0b23d64b-63df-4060-b2a6-150321514216'	System	10 Aug 2020 20:18:49
User entered 'None (1)'	System	10 Aug 2020 20:18:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:47', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0b23d64b-63df-4060-b2a6-150321514216' User entered '10 Aug 2020 13:18'	System	10 Aug 2020 20:18:49
	System	10 Aug 2020 20:18:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 6'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:37', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '30cc3442-14e3-4cb0-89b1-c28bd96a6283'	System	11 Aug 2020 19:15:49
User entered 'None (1)'	System	11 Aug 2020 19:15:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '30cc3442-14e3-4cb0-89b1-c28bd96a6283'	System	11 Aug 2020 19:15:49
User entered 'No (N)'	System	11 Aug 2020 19:15:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '30cc3442-14e3-4cb0-89b1-c28bd96a6283'	System	11 Aug 2020 19:15:49
User entered 'No (N)'	System	11 Aug 2020 19:15:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '30cc3442-14e3-4cb0-89b1-c28bd96a6283'	System	11 Aug 2020 19:15:49
User entered 'None (1)'	System	11 Aug 2020 19:15:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '30cc3442-14e3-4cb0-89b1-c28bd96a6283'	System	11 Aug 2020 19:15:49
User entered '11 Aug 2020 12:15'	System	11 Aug 2020 19:15:49

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 7'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6799413-c4e4-49ea-9ca9-78990696f907'	System	12 Aug 2020 19:00:54
User entered 'None (1)'	System	12 Aug 2020 19:00:54

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:44', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6799413-c4e4-49ea-9ca9-78990696f907'	System	12 Aug 2020 19:00:54
User entered 'No (N)'	System	12 Aug 2020 19:00:54

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6799413-c4e4-49ea-9ca9-78990696f907'	System	12 Aug 2020 19:00:54
User entered 'No (N)'	System	12 Aug 2020 19:00:54

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6799413-c4e4-49ea-9ca9-78990696f907'	System	12 Aug 2020 19:00:54
User entered 'None (1)'	System	12 Aug 2020 19:00:54

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6799413-c4e4-49ea-9ca9-78990696f907'	System	12 Aug 2020 19:00:54
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 19:00:54

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:20:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:20:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:20:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:20:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:20:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:21:01', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'None (0)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:21:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered 'No (N)'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T13:21:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1939bd69-d934-4503-af83-8722cd4cb1eb' User entered '06 Aug 2020 13:21'	System	06 Aug 2020 20:21:10
	System	06 Aug 2020 20:21:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 13:03'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 15:33'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'None (0)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539'	System	07 Aug 2020 00:21:37
User entered 'No interference with activity (1)'	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'None (0)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'None (0)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'None (0)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'None (0)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered 'No (N)'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-06T17:21:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c6207aa1-11ba-4535-9318-83cfc8bfe539' User entered '06 Aug 2020 17:21'	System	07 Aug 2020 00:21:37
	System	07 Aug 2020 00:21:37

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Aug 2020 16:28'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 2'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:18', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:21', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:25', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'None (0)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:28', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered 'No (N)'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-07T12:24:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e18a9ae7-47ba-433a-9c14-793303933c1f' User entered '07 Aug 2020 12:24'	System	07 Aug 2020 19:24:36
	System	07 Aug 2020 19:24:36

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 3'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered 'None (0)'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered 'None (0)'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered 'None (0)'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered 'None (0)'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered 'None (0)'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7'	System	08 Aug 2020 20:08:53
User entered 'None (0)'	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:49', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7'	System	08 Aug 2020 20:08:53
User entered 'No (N)'	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-08T13:08:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d65d827-d363-4b3e-ba81-3a657c4b1fe7' User entered '08 Aug 2020 13:08'	System	08 Aug 2020 20:08:53
	System	08 Aug 2020 20:08:53

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 4'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:17', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'None (0)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered 'No (N)'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-09T15:21:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3d09126f-eea6-499e-bf26-618fb1e210fc' User entered '09 Aug 2020 15:21'	System	09 Aug 2020 22:21:30
	System	09 Aug 2020 22:21:30

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 5'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:18:58', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:19:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'None (0)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:19:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered 'No (N)'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-10T13:19:05', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '978bbe32-8267-46c0-a536-309e3729865a' User entered '10 Aug 2020 13:19'	System	10 Aug 2020 20:19:09
	System	10 Aug 2020 20:19:09

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 6'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:57', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:15:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:16:01', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:16:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'None (0)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:16:05', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b' User entered 'No (N)'	System	11 Aug 2020 19:16:11
	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-11T12:16:08', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '46b95955-f114-4886-8486-4fb4595a303b'	System	11 Aug 2020 19:16:11
User entered '11 Aug 2020 12:16'	System	11 Aug 2020 19:16:11

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 7'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:57', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:00:58', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:01:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:01:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'None (0)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:01:06', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered 'No (N)'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-08-12T12:01:08', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '04b5765f-4cc7-4dd1-ae82-20fd9aa2f0eb' User entered '12 Aug 2020 12:01'	System	12 Aug 2020 19:01:10
	System	12 Aug 2020 19:01:10

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 19:50:05

US3162068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:42:42

US3162068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '13 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:42:42

US3162068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:42:42

US3162068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:42:42

US3162068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	14 Aug 2020 04:42:47

US3162068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	14 Aug 2020 04:42:47

US3162068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:03:35

US3162068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:03:35

US3162068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:03:35

US3162068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:03:35

US3162068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	21 Aug 2020 05:03:38

US3162068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	21 Aug 2020 05:03:38

US3162068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:01:31

US3162068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '27 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:01:31

US3162068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:01:31

US3162068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:01:31

US3162068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 17:01:43

US3162068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	31 Aug 2020 17:01:43

US3162068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:17:04

US3162068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:17:04

US3162068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 20:17:04

US3162068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'VISIT2'	System	04 Sep 2020 20:17:04

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4)	07 Sep 2020 18:30:56
	(b) (4)	

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '13:08'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered '04 Sep 2020 13:08'	System	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '36.3' C	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '79'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'bpm'	System	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '15'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'breaths/min'	System	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '117'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '70'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	07 Sep 2020 18:30:56

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '15:06'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered '04 Sep 2020 15:06'	System	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '36.4' C	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '79'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'bpm'	System	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '16'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'breaths/min'	System	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '119'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '77'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	07 Sep 2020 18:31:32

US3162068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:42

US3162068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:42

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '14:30'	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '4 Sep 2020 14:30'	System	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'ONCE'	System	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:37:58

US3162068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:55

US3162068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:55

US3162068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '13:25'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:31:55

US3162068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '04 Sep 2020 13:25'	System	07 Sep 2020 18:31:55

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '13:30'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '04 Sep 2020 13:30'	System	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered empty.	System	07 Sep 2020 18:32:22

US3162068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 18:32:27

US3162068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered '1'	System	07 Sep 2020 18:32:27

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fe7cb25e-abf0-4e8c-979f-f3b555d18993' User entered 'Yes (Y)'	System	04 Sep 2020 22:01:20
	System	04 Sep 2020 22:01:20

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fe7cb25e-abf0-4e8c-979f-f3b555d18993' User entered '97.6'	System	04 Sep 2020 22:01:20
	System	04 Sep 2020 22:01:20

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:12', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fe7cb25e-abf0-4e8c-979f-f3b555d18993'	System	04 Sep 2020 22:01:20
User entered 'No (N)'	System	04 Sep 2020 22:01:20

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:17', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fe7cb25e-abf0-4e8c-979f-f3b555d18993' User entered '04 Sep 2020 15:01'	System	04 Sep 2020 22:01:20
	System	04 Sep 2020 22:01:20

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 14:50'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 17:20'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '64d39c64-bfb5-4b3b-9940-680806e7f181' User entered 'Yes (Y)'	System	05 Sep 2020 01:50:25
	System	05 Sep 2020 01:50:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:17', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '64d39c64-bfb5-4b3b-9940-680806e7f181' User entered '97.6'	System	05 Sep 2020 01:50:25
	System	05 Sep 2020 01:50:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '64d39c64-bfb5-4b3b-9940-680806e7f181' User entered 'No (N)'	System	05 Sep 2020 01:50:25
	System	05 Sep 2020 01:50:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '64d39c64-bfb5-4b3b-9940-680806e7f181' User entered '04 Sep 2020 18:50'	System	05 Sep 2020 01:50:25
	System	05 Sep 2020 01:50:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 18:15'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 2'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:33:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dd884dee-6447-41c7-b957-cafe50e57a7c' User entered 'Yes (Y)'	System	05 Sep 2020 19:34:07
	System	05 Sep 2020 19:34:07

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:33:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dd884dee-6447-41c7-b957-cafe50e57a7c' User entered '98.2'	System	05 Sep 2020 19:34:07
	System	05 Sep 2020 19:34:07

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:33:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dd884dee-6447-41c7-b957-cafe50e57a7c'	System	05 Sep 2020 19:34:07
User entered 'No (N)'	System	05 Sep 2020 19:34:07

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dd884dee-6447-41c7-b957-cafe50e57a7c' User entered '05 Sep 2020 12:34'	System	05 Sep 2020 19:34:07
	System	05 Sep 2020 19:34:07

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 3'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:39', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5a50d358-2633-4171-9c08-5a36f551ba36' User entered 'Yes (Y)'	System	07 Sep 2020 16:51:54
	System	07 Sep 2020 16:51:54

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5a50d358-2633-4171-9c08-5a36f551ba36' User entered '98.3'	System	07 Sep 2020 16:51:54
	System	07 Sep 2020 16:51:54

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:49', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5a50d358-2633-4171-9c08-5a36f551ba36'	System	07 Sep 2020 16:51:54
User entered 'No (N)'	System	07 Sep 2020 16:51:54

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5a50d358-2633-4171-9c08-5a36f551ba36' User entered '07 Sep 2020 09:51'	System	07 Sep 2020 16:51:54
	System	07 Sep 2020 16:51:54

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 4'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:23:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'cd9b2966-7e82-4952-b5dc-c93ea0f13c68' User entered 'Yes (Y)'	System	07 Sep 2020 19:24:00
	System	07 Sep 2020 19:24:00

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:23:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'cd9b2966-7e82-4952-b5dc-c93ea0f13c68' User entered '98.5'	System	07 Sep 2020 19:24:00
	System	07 Sep 2020 19:24:00

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:23:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'cd9b2966-7e82-4952-b5dc-c93ea0f13c68'	System	07 Sep 2020 19:24:00
User entered 'No (N)'	System	07 Sep 2020 19:24:00

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:23:58', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'cd9b2966-7e82-4952-b5dc-c93ea0f13c68' User entered '07 Sep 2020 12:23'	System	07 Sep 2020 19:24:00
	System	07 Sep 2020 19:24:00

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 5'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:00:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '546d943f-bc79-4824-845a-cf941cfc6830' User entered 'Yes (Y)'	System	08 Sep 2020 19:00:58
	System	08 Sep 2020 19:00:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:00:36', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '546d943f-bc79-4824-845a-cf941cfc6830' User entered '97.9'	System	08 Sep 2020 19:00:58
	System	08 Sep 2020 19:00:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:00:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '546d943f-bc79-4824-845a-cf941cfc6830'	System	08 Sep 2020 19:00:58
User entered 'No (N)'	System	08 Sep 2020 19:00:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:00:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '546d943f-bc79-4824-845a-cf941cfc6830' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:00:58
	System	08 Sep 2020 19:00:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 6'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:08', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9537bb7-a8d2-4dc3-95ac-ddf68e8ab246' User entered 'Yes (Y)'	System	09 Sep 2020 19:03:32
	System	09 Sep 2020 19:03:32

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:18', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9537bb7-a8d2-4dc3-95ac-ddf68e8ab246' User entered '97.9'	System	09 Sep 2020 19:03:32
	System	09 Sep 2020 19:03:32

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9537bb7-a8d2-4dc3-95ac-ddf68e8ab246' User entered 'No (N)'	System	09 Sep 2020 19:03:32
	System	09 Sep 2020 19:03:32

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:26', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9537bb7-a8d2-4dc3-95ac-ddf68e8ab246' User entered '09 Sep 2020 12:03'	System	09 Sep 2020 19:03:32
	System	09 Sep 2020 19:03:32

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 7'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:06', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd8d17209-e330-45d5-85f6-8b7a26efd012'	System	10 Sep 2020 19:07:25
User entered 'Yes (Y)'	System	10 Sep 2020 19:07:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd8d17209-e330-45d5-85f6-8b7a26efd012' User entered '98.4'	System	10 Sep 2020 19:07:25
	System	10 Sep 2020 19:07:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:17', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd8d17209-e330-45d5-85f6-8b7a26efd012'	System	10 Sep 2020 19:07:25
User entered 'No (N)'	System	10 Sep 2020 19:07:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd8d17209-e330-45d5-85f6-8b7a26efd012'	System	10 Sep 2020 19:07:25
User entered '10 Sep 2020 12:07'	System	10 Sep 2020 19:07:25

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a37463eb-89c7-492e-b1ba-7b62d045b09f'	System	04 Sep 2020 22:01:39
User entered 'None (1)'	System	04 Sep 2020 22:01:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:26', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a37463eb-89c7-492e-b1ba-7b62d045b09f' User entered 'No (N)'	System	04 Sep 2020 22:01:39
	System	04 Sep 2020 22:01:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a37463eb-89c7-492e-b1ba-7b62d045b09f' User entered 'No (N)'	System	04 Sep 2020 22:01:39
	System	04 Sep 2020 22:01:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a37463eb-89c7-492e-b1ba-7b62d045b09f'	System	04 Sep 2020 22:01:39
User entered 'None (1)'	System	04 Sep 2020 22:01:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:34', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'a37463eb-89c7-492e-b1ba-7b62d045b09f' User entered '04 Sep 2020 15:01'	System	04 Sep 2020 22:01:39
	System	04 Sep 2020 22:01:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 14:50'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 17:20'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e0a95f1-a95d-4b8d-8491-bb4a96e537b8'	System	05 Sep 2020 01:50:39
User entered 'None (1)'	System	05 Sep 2020 01:50:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e0a95f1-a95d-4b8d-8491-bb4a96e537b8' User entered 'No (N)'	System	05 Sep 2020 01:50:39
	System	05 Sep 2020 01:50:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:33', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e0a95f1-a95d-4b8d-8491-bb4a96e537b8' User entered 'No (N)'	System	05 Sep 2020 01:50:39
	System	05 Sep 2020 01:50:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e0a95f1-a95d-4b8d-8491-bb4a96e537b8' User entered 'None (1)'	System	05 Sep 2020 01:50:39
	System	05 Sep 2020 01:50:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:37', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e0a95f1-a95d-4b8d-8491-bb4a96e537b8' User entered '04 Sep 2020 18:50'	System	05 Sep 2020 01:50:39
	System	05 Sep 2020 01:50:39

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 18:15'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 2'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e0fdcdf-ca5b-4738-8aaf-ddf51ff8dec8'	System	05 Sep 2020 19:34:18
User entered 'None (1)'	System	05 Sep 2020 19:34:18

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:10', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e0fdcdf-ca5b-4738-8aaf-ddf51ff8dec8'	System	05 Sep 2020 19:34:18
User entered 'No (N)'	System	05 Sep 2020 19:34:18

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:12', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e0fdcdf-ca5b-4738-8aaf-ddf51ff8dec8'	System	05 Sep 2020 19:34:18
User entered 'No (N)'	System	05 Sep 2020 19:34:18

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e0fdcdf-ca5b-4738-8aaf-ddf51ff8dec8'	System	05 Sep 2020 19:34:18
User entered 'None (1)'	System	05 Sep 2020 19:34:18

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9e0fdcdf-ca5b-4738-8aaf-ddf51ff8dec8' User entered '05 Sep 2020 12:34'	System	05 Sep 2020 19:34:18
	System	05 Sep 2020 19:34:18

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 3'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b4e79983-6428-4c33-b2d4-224c6afae725'	System	07 Sep 2020 16:52:07
User entered 'None (1)'	System	07 Sep 2020 16:52:07

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:51:58', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b4e79983-6428-4c33-b2d4-224c6afae725'	System	07 Sep 2020 16:52:07
User entered 'No (N)'	System	07 Sep 2020 16:52:07

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b4e79983-6428-4c33-b2d4-224c6afae725'	System	07 Sep 2020 16:52:07
User entered 'No (N)'	System	07 Sep 2020 16:52:07

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:02', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b4e79983-6428-4c33-b2d4-224c6afae725'	System	07 Sep 2020 16:52:07
User entered 'None (1)'	System	07 Sep 2020 16:52:07

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:05', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b4e79983-6428-4c33-b2d4-224c6afae725'	System	07 Sep 2020 16:52:07
User entered '07 Sep 2020 09:52'	System	07 Sep 2020 16:52:07

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 4'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:02', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e0622907-0805-4309-a433-6a8a0d10f024' User entered 'None (1)'	System	07 Sep 2020 19:24:13
	System	07 Sep 2020 19:24:13

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e0622907-0805-4309-a433-6a8a0d10f024' User entered 'No (N)'	System	07 Sep 2020 19:24:13
	System	07 Sep 2020 19:24:13

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e0622907-0805-4309-a433-6a8a0d10f024'	System	07 Sep 2020 19:24:13
User entered 'No (N)'	System	07 Sep 2020 19:24:13

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e0622907-0805-4309-a433-6a8a0d10f024' User entered 'None (1)'	System	07 Sep 2020 19:24:13
	System	07 Sep 2020 19:24:13

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:12', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e0622907-0805-4309-a433-6a8a0d10f024' User entered '07 Sep 2020 12:24'	System	07 Sep 2020 19:24:13
	System	07 Sep 2020 19:24:13

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 5'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:00:57', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4b91eaaf-aa9e-49f7-b0a5-81a0592525bd' User entered 'None (1)'	System	08 Sep 2020 19:01:14
	System	08 Sep 2020 19:01:14

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:01', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4b91eaaf-aa9e-49f7-b0a5-81a0592525bd' User entered 'No (N)'	System	08 Sep 2020 19:01:14
	System	08 Sep 2020 19:01:14

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4b91eaaf-aa9e-49f7-b0a5-81a0592525bd' User entered 'No (N)'	System	08 Sep 2020 19:01:14
	System	08 Sep 2020 19:01:14

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:04', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4b91eaaf-aa9e-49f7-b0a5-81a0592525bd' User entered 'None (1)'	System	08 Sep 2020 19:01:14
	System	08 Sep 2020 19:01:14

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:10', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4b91eaaf-aa9e-49f7-b0a5-81a0592525bd' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 19:01:14
	System	08 Sep 2020 19:01:14

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 6'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e3f04197-f735-4469-873b-cf1a298e9f63'	System	09 Sep 2020 19:03:43
User entered 'None (1)'	System	09 Sep 2020 19:03:43

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e3f04197-f735-4469-873b-cf1a298e9f63'	System	09 Sep 2020 19:03:43
User entered 'No (N)'	System	09 Sep 2020 19:03:43

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e3f04197-f735-4469-873b-cf1a298e9f63'	System	09 Sep 2020 19:03:43
User entered 'No (N)'	System	09 Sep 2020 19:03:43

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e3f04197-f735-4469-873b-cf1a298e9f63'	System	09 Sep 2020 19:03:43
User entered 'None (1)'	System	09 Sep 2020 19:03:43

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e3f04197-f735-4469-873b-cf1a298e9f63' User entered '09 Sep 2020 12:03'	System	09 Sep 2020 19:03:43
	System	09 Sep 2020 19:03:43

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 7'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'f9fea434-d135-4c5a-9403-7a1e693690ac'	System	10 Sep 2020 19:07:36
User entered 'None (1)'	System	10 Sep 2020 19:07:36

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:25', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'f9fea434-d135-4c5a-9403-7a1e693690ac' User entered 'No (N)'	System	10 Sep 2020 19:07:36
	System	10 Sep 2020 19:07:36

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'f9fea434-d135-4c5a-9403-7a1e693690ac' User entered 'No (N)'	System	10 Sep 2020 19:07:36
	System	10 Sep 2020 19:07:36

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'f9fea434-d135-4c5a-9403-7a1e693690ac'	System	10 Sep 2020 19:07:36
User entered 'None (1)'	System	10 Sep 2020 19:07:36

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'f9fea434-d135-4c5a-9403-7a1e693690ac' User entered '10 Sep 2020 12:07'	System	10 Sep 2020 19:07:36
	System	10 Sep 2020 19:07:36

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:44', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'None (0)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered 'No (N)'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T15:01:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9488d2b0-1553-48b2-9a11-e2b063710cf6' User entered '04 Sep 2020 15:01'	System	04 Sep 2020 22:01:55
	System	04 Sep 2020 22:01:55

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 14:50'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 17:20'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:44', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:49', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'None (0)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered 'No (N)'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-04T18:50:57', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'fcf7c8fe-6fec-40cd-8385-6bfb18ccb501' User entered '04 Sep 2020 18:50'	System	05 Sep 2020 01:51:00
	System	05 Sep 2020 01:51:00

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '04 Sep 2020 18:15'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 2'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:26', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:28', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered 'None (0)'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7'	System	05 Sep 2020 19:34:36
User entered 'No (N)'	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-05T12:34:33', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '01855247-8d3b-4516-acfd-ec83f9a97ed7' User entered '05 Sep 2020 12:34'	System	05 Sep 2020 19:34:36
	System	05 Sep 2020 19:34:36

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 3'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:11', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'None (0)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:23', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered 'No (N)'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T09:52:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b2e446c-533e-4da8-a67e-1cfb0b76f12f' User entered '07 Sep 2020 09:52'	System	07 Sep 2020 16:52:27
	System	07 Sep 2020 16:52:27

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 4'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:17', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:21', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:26', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'None (0)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:29', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered 'No (N)'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-07T12:24:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43568a42-9eb1-408b-9722-bddc8efdc58c' User entered '07 Sep 2020 12:24'	System	07 Sep 2020 19:24:35
	System	07 Sep 2020 19:24:35

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 5'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33'	System	08 Sep 2020 19:01:38
User entered 'None (0)'	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:18', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered 'None (0)'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered 'None (0)'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered 'None (0)'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered 'None (0)'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:26', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered 'None (0)'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:30', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33'	System	08 Sep 2020 19:01:38
User entered 'No (N)'	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-08T12:01:32', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8062d437-6864-4a39-bd4a-d2799dddcf33' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 19:01:38
	System	08 Sep 2020 19:01:38

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 6'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered 'None (0)'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:03:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3'	System	09 Sep 2020 19:04:09
User entered 'No (N)'	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-09T12:04:02', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e926bb27-4815-45d8-8a86-e5db8ad07ad3' User entered '09 Sep 2020 12:04'	System	09 Sep 2020 19:04:09
	System	09 Sep 2020 19:04:09

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	04 Sep 2020 21:37:58
User entered 'Day 7'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:35', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:36', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:38', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'None (0)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered 'No (N)'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-09-10T12:07:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '610884f9-3cf5-4ad4-bcc9-6c4b4a54c5ec' User entered '10 Sep 2020 12:07'	System	10 Sep 2020 19:07:54
	System	10 Sep 2020 19:07:54

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:37:58

US3162068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:37:58

US3162068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:09:56

US3162068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 21:43:20
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed date correct.' (Site from System).	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:11:25
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 18:09:56
User entered '10 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:09:56

US3162068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:09:56

US3162068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	11 Sep 2020 18:09:56
	(b) (4)	

US3162068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	11 Sep 2020 18:09:45

US3162068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	11 Sep 2020 18:09:45

US3162068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 16:38:11

US3162068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '18 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 16:38:11

US3162068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 16:38:11

US3162068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 16:38:11

US3162068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 16:38:16

US3162068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	21 Sep 2020 16:38:16

US3162068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:23:26

US3162068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 16:23:26
	(b) (4)	

US3162068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:23:26

US3162068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:23:26

US3162068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:23:30

US3162068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	28 Sep 2020 16:23:30

US3162068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:06:29

US3162068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '2 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:06:29

US3162068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[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 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:06:29

US3162068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'VISIT3'	System	03 Oct 2020 04:06:29

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '2 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '10:16'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered '2 Oct 2020 10:16'	System	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '97.0' F	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '78'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'bpm'	System	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'breaths/min'	System	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '105'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 13:31:11
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Judith Kirstein (b) (4) (b) (4)	03 Oct 2020 22:58:12
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Oct 2020 22:57:59
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Oct 2020 22:57:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Oct 2020 22:57:59
User entered '57' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Oct 2020 22:57:59
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Oct 2020 04:08:43
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	03 Oct 2020 04:08:43
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Oct 2020 04:08:43
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:08:43
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Oct 2020 04:07:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '57'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'mmHg'	System	03 Oct 2020 22:57:59
User entered empty.	System	03 Oct 2020 04:08:43
User entered 'mmHg'	System	03 Oct 2020 04:07:17

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49

US3162068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49

US3162068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:02

US3162068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:02

US3162068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:13

US3162068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '2 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:13

US3162068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '10:32'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:13

US3162068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered '2 Oct 2020 10:32'	System	03 Oct 2020 04:09:13

US3162068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	03 Oct 2020 04:09:20

US3162068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:49
User entered 'I'	System	03 Oct 2020 04:09:20

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 64'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-08T10:28:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcb17e7c-03e1-4fbb-8309-0c779eca62f0' User entered 'No (N)'	System	08 Oct 2020 17:28:25
	System	08 Oct 2020 17:28:25

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-08T10:28:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcb17e7c-03e1-4fbb-8309-0c779eca62f0'	System	08 Oct 2020 17:28:25
User entered 'No (N)'	System	08 Oct 2020 17:28:25

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-08T10:28:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcb17e7c-03e1-4fbb-8309-0c779eca62f0' User entered '08 Oct 2020 10:28:22'	System	08 Oct 2020 17:28:25
	System	08 Oct 2020 17:28:25

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 71'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-15T12:00:39', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b2ead213-edca-402d-a3bd-e24adae86093'	System	15 Oct 2020 19:00:53
User entered 'No (N)'	System	15 Oct 2020 19:00:53

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-15T12:00:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b2ead213-edca-402d-a3bd-e24adae86093'	System	15 Oct 2020 19:00:53
User entered 'No (N)'	System	15 Oct 2020 19:00:53

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-15T12:00:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b2ead213-edca-402d-a3bd-e24adae86093' User entered '15 Oct 2020 12:00:46'	System	15 Oct 2020 19:00:53
	System	15 Oct 2020 19:00:53

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 78'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-20T20:47:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d87f0e1-0673-4e71-8366-9d3bf09978fe' User entered 'No (N)'	System	21 Oct 2020 03:47:47
	System	21 Oct 2020 03:47:47

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-20T20:47:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d87f0e1-0673-4e71-8366-9d3bf09978fe' User entered 'No (N)'	System	21 Oct 2020 03:47:47
	System	21 Oct 2020 03:47:47

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-10-20T20:47:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '0d87f0e1-0673-4e71-8366-9d3bf09978fe' User entered '20 Oct 2020 20:47:45'	System	21 Oct 2020 03:47:47
	System	21 Oct 2020 03:47:47

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 92'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-03T21:01:16', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6fb54024-f322-4be4-9974-d922c8a19350'	System	04 Nov 2020 05:02:18
User entered 'No (N)'	System	04 Nov 2020 05:02:18

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-03T21:01:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6fb54024-f322-4be4-9974-d922c8a19350'	System	04 Nov 2020 05:02:18
User entered 'No (N)'	System	04 Nov 2020 05:02:18

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-03T21:01:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6fb54024-f322-4be4-9974-d922c8a19350' User entered '03 Nov 2020 21:01:24'	System	04 Nov 2020 05:02:18
	System	04 Nov 2020 05:02:18

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 99'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-10T08:05:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9109a02-599f-4890-8739-4675e72342c7'	System	10 Nov 2020 16:05:59
User entered 'No (N)'	System	10 Nov 2020 16:05:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-10T08:05:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9109a02-599f-4890-8739-4675e72342c7'	System	10 Nov 2020 16:05:59
User entered 'No (N)'	System	10 Nov 2020 16:05:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-10T08:05:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'b9109a02-599f-4890-8739-4675e72342c7' User entered '10 Nov 2020 08:05:56'	System	10 Nov 2020 16:05:59
	System	10 Nov 2020 16:05:59

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered 'Day 106'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-17T11:36:03', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9cfdeafd-2c8e-4389-8238-b0b738921a45'	System	17 Nov 2020 19:36:19
User entered 'No (N)'	System	17 Nov 2020 19:36:19

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-17T11:36:08', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9cfdeafd-2c8e-4389-8238-b0b738921a45'	System	17 Nov 2020 19:36:19
User entered 'No (N)'	System	17 Nov 2020 19:36:19

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-11-17T11:36:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9cfdeafd-2c8e-4389-8238-b0b738921a45' User entered '17 Nov 2020 11:36:14'	System	17 Nov 2020 19:36:19
	System	17 Nov 2020 19:36:19

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 19:50:05

US3162068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:41:35
Data entry locked.	System	06 Aug 2020 19:50:05
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 19:50:05

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-01T13:49:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e3fab2d-0c20-4afc-b27b-670a25f15f39'	System	01 Dec 2020 21:49:48
User entered 'No (N)'	System	01 Dec 2020 21:49:48

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-01T13:49:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e3fab2d-0c20-4afc-b27b-670a25f15f39'	System	01 Dec 2020 21:49:48
User entered 'No (N)'	System	01 Dec 2020 21:49:48

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-01T13:49:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5e3fab2d-0c20-4afc-b27b-670a25f15f39' User entered '01 Dec 2020 13:49:46'	System	01 Dec 2020 21:49:48
	System	01 Dec 2020 21:49:48

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-07T12:00:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4ec4640c-65d3-4916-96b8-adad75fb1ed2' User entered 'No (N)'	System	07 Dec 2020 20:00:29
	System	07 Dec 2020 20:00:29

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-07T12:00:22', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4ec4640c-65d3-4916-96b8-adad75fb1ed2'	System	07 Dec 2020 20:00:29
User entered 'No (N)'	System	07 Dec 2020 20:00:29

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-07T12:00:25', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '4ec4640c-65d3-4916-96b8-adad75fb1ed2' User entered '07 Dec 2020 12:00:25'	System	07 Dec 2020 20:00:29
	System	07 Dec 2020 20:00:29

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-15T18:59:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '38c260ea-2bee-4b90-94ac-03a590bb349f' User entered 'No (N)'	System	16 Dec 2020 03:00:05
	System	16 Dec 2020 03:00:05

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-15T18:59:57', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '38c260ea-2bee-4b90-94ac-03a590bb349f' User entered 'No (N)'	System	16 Dec 2020 03:00:05
	System	16 Dec 2020 03:00:05

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-15T18:59:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '38c260ea-2bee-4b90-94ac-03a590bb349f' User entered '15 Dec 2020 18:59:59'	System	16 Dec 2020 03:00:05
	System	16 Dec 2020 03:00:05

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-19T07:30:01', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43ea11c5-e3d8-4c35-96f5-32707c2d27b3' User entered 'No (N)'	System	19 Dec 2020 15:30:22
	System	19 Dec 2020 15:30:22

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-19T07:30:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43ea11c5-e3d8-4c35-96f5-32707c2d27b3' User entered 'No (N)'	System	19 Dec 2020 15:30:22
	System	19 Dec 2020 15:30:22

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-19T07:30:18', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '43ea11c5-e3d8-4c35-96f5-32707c2d27b3' User entered '19 Dec 2020 07:30:18'	System	19 Dec 2020 15:30:22
	System	19 Dec 2020 15:30:22

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-26T07:35:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '411caea0-5fcb-4c78-b756-ce86bd21bf47'	System	26 Dec 2020 15:36:03
User entered 'No (N)'	System	26 Dec 2020 15:36:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-26T07:35:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '411caea0-5fcb-4c78-b756-ce86bd21bf47'	System	26 Dec 2020 15:36:03
User entered 'No (N)'	System	26 Dec 2020 15:36:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2020-12-26T07:35:59', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '411caea0-5fcb-4c78-b756-ce86bd21bf47' User entered '26 Dec 2020 07:35:59'	System	26 Dec 2020 15:36:03
	System	26 Dec 2020 15:36:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-02T07:59:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1c8cb6ea-7053-46f2-a58e-d03c8ccb5b43' User entered 'No (N)'	System	02 Jan 2021 15:59:39
	System	02 Jan 2021 15:59:39

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-02T07:59:33', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1c8cb6ea-7053-46f2-a58e-d03c8ccb5b43'	System	02 Jan 2021 15:59:39
User entered 'No (N)'	System	02 Jan 2021 15:59:39

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-02T07:59:36', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '1c8cb6ea-7053-46f2-a58e-d03c8ccb5b43' User entered '02 Jan 2021 07:59:36'	System	02 Jan 2021 15:59:39
	System	02 Jan 2021 15:59:39

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-09T07:56:11', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5b308267-2c7b-4214-9788-2e575d280737'	System	09 Jan 2021 15:56:19
User entered 'No (N)'	System	09 Jan 2021 15:56:19

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-09T07:56:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5b308267-2c7b-4214-9788-2e575d280737'	System	09 Jan 2021 15:56:19
User entered 'No (N)'	System	09 Jan 2021 15:56:19

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-09T07:56:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '5b308267-2c7b-4214-9788-2e575d280737'	System	09 Jan 2021 15:56:19
User entered '09 Jan 2021 07:56:15'	System	09 Jan 2021 15:56:19

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-16T08:23:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8ff9e68d-7343-4c7c-bcb9-da6964cca5a2'	System	16 Jan 2021 16:23:56
User entered 'No (N)'	System	16 Jan 2021 16:23:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-16T08:23:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8ff9e68d-7343-4c7c-bcb9-da6964cca5a2'	System	16 Jan 2021 16:23:56
User entered 'No (N)'	System	16 Jan 2021 16:23:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-16T08:23:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '8ff9e68d-7343-4c7c-bcb9-da6964cca5a2'	System	16 Jan 2021 16:23:56
User entered '16 Jan 2021 08:23:53'	System	16 Jan 2021 16:23:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:04:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72' User entered 'Yes (Y)'	System	23 Jan 2021 16:05:24
	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:04:46', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72'	System	23 Jan 2021 16:05:24
User entered 'No (N)'	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:04:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72' User entered 'No (N)'	System	23 Jan 2021 16:05:24
	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:04:58', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72' User entered 'Yes (Y)'	System	23 Jan 2021 16:05:24
	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Please 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:05:10', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72'	System	23 Jan 2021 16:05:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-23T08:05:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'c68d0328-a650-4519-9d4f-7eac24340d72' User entered '23 Jan 2021 08:05:14'	System	23 Jan 2021 16:05:24
	System	23 Jan 2021 16:05:24

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-30T07:29:28', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '69803335-da08-4891-acaa-21de972a7500' User entered 'No (N)'	System	30 Jan 2021 15:29:37

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-30T07:29:31', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '69803335-da08-4891-acaa-21de972a7500'	System	30 Jan 2021 15:29:37
User entered 'No (N)'	System	30 Jan 2021 15:29:37

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-01-30T07:29:34', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '69803335-da08-4891-acaa-21de972a7500' User entered '30 Jan 2021 07:29:34'	System	30 Jan 2021 15:29:37
	System	30 Jan 2021 15:29:37

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-06T07:35:05', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '15218396-8bc8-4e0d-890f-20563ce584a3' User entered 'No (N)'	System	06 Feb 2021 15:35:15
	System	06 Feb 2021 15:35:15

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-06T07:35:09', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '15218396-8bc8-4e0d-890f-20563ce584a3' User entered 'No (N)'	System	06 Feb 2021 15:35:15
	System	06 Feb 2021 15:35:15

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-06T07:35:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '15218396-8bc8-4e0d-890f-20563ce584a3' User entered '06 Feb 2021 07:35:13'	System	06 Feb 2021 15:35:15
	System	06 Feb 2021 15:35:15

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-13T08:50:37', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9d737f67-1d5d-4176-a965-f5351e2b2c13' User entered 'No (N)'	System	13 Feb 2021 16:50:46
	System	13 Feb 2021 16:50:46

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-13T08:50:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9d737f67-1d5d-4176-a965-f5351e2b2c13' User entered 'No (N)'	System	13 Feb 2021 16:50:46

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-13T08:50:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '9d737f67-1d5d-4176-a965-f5351e2b2c13' User entered '13 Feb 2021 08:50:43'	System	13 Feb 2021 16:50:46
	System	13 Feb 2021 16:50:46

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-20T07:51:42', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'ec4e0b6d-e91d-4413-ba5a-c0e2310d009d' User entered 'Yes (Y)'	System	20 Feb 2021 15:52:25
	System	20 Feb 2021 15:52:25

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-20T07:51:52', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'ec4e0b6d-e91d-4413-ba5a-c0e2310d009d' User entered 'No (N)'	System	20 Feb 2021 15:52:25
	System	20 Feb 2021 15:52:25

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-20T07:52:01', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'ec4e0b6d-e91d-4413-ba5a-c0e2310d009d' User entered 'No (N)'	System	20 Feb 2021 15:52:25
	System	20 Feb 2021 15:52:25

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-20T07:52:07', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'ec4e0b6d-e91d-4413-ba5a-c0e2310d009d' User entered 'No (N)'	System	20 Feb 2021 15:52:25
	System	20 Feb 2021 15:52:25

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-20T07:52:21', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'ec4e0b6d-e91d-4413-ba5a-c0e2310d009d' User entered '20 Feb 2021 07:52:21'	System	20 Feb 2021 15:52:25
	System	20 Feb 2021 15:52:25

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-27T08:01:53', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '7ff8ecb3-5be8-4991-8e3f-5ca78411fc0d' User entered 'No (N)'	System	27 Feb 2021 16:02:03
	System	27 Feb 2021 16:02:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-27T08:01:56', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '7ff8ecb3-5be8-4991-8e3f-5ca78411fc0d' User entered 'No (N)'	System	27 Feb 2021 16:02:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-27T08:02:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '7ff8ecb3-5be8-4991-8e3f-5ca78411fc0d' User entered '27 Feb 2021 08:02:00'	System	27 Feb 2021 16:02:03
	System	27 Feb 2021 16:02:03

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-06T10:28:20', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '05586da4-b247-4fe3-8f54-f437159de954'	System	06 Mar 2021 18:28:31
User entered 'No (N)'	System	06 Mar 2021 18:28:31

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-06T10:28:24', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '05586da4-b247-4fe3-8f54-f437159de954'	System	06 Mar 2021 18:28:31
User entered 'No (N)'	System	06 Mar 2021 18:28:31

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-06T10:28:27', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '05586da4-b247-4fe3-8f54-f437159de954' User entered '06 Mar 2021 10:28:27'	System	06 Mar 2021 18:28:31
	System	06 Mar 2021 18:28:31

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-13T08:43:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3bc770e6-008b-46b8-acbd-c8347380ca29'	System	13 Mar 2021 16:43:21
User entered 'No (N)'	System	13 Mar 2021 16:43:21

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-13T08:43:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3bc770e6-008b-46b8-acbd-c8347380ca29'	System	13 Mar 2021 16:43:21
User entered 'No (N)'	System	13 Mar 2021 16:43:21

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-13T08:43:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '3bc770e6-008b-46b8-acbd-c8347380ca29' User entered '13 Mar 2021 08:43:19'	System	13 Mar 2021 16:43:21
	System	13 Mar 2021 16:43:21

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-20T08:31:48', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '471883e0-1c4d-4dd4-8613-abc9720d2273'	System	20 Mar 2021 15:31:56
User entered 'No (N)'	System	20 Mar 2021 15:31:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-20T08:31:50', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '471883e0-1c4d-4dd4-8613-abc9720d2273'	System	20 Mar 2021 15:31:56
User entered 'No (N)'	System	20 Mar 2021 15:31:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-20T08:31:54', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '471883e0-1c4d-4dd4-8613-abc9720d2273' User entered '20 Mar 2021 08:31:54'	System	20 Mar 2021 15:31:56
	System	20 Mar 2021 15:31:56

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-27T08:07:13', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b1edd44-c9f3-405a-8a62-4ac8d78c658d' User entered 'No (N)'	System	27 Mar 2021 15:07:20
	System	27 Mar 2021 15:07:20

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-27T08:07:15', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b1edd44-c9f3-405a-8a62-4ac8d78c658d'	System	27 Mar 2021 15:07:20
User entered 'No (N)'	System	27 Mar 2021 15:07:20

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-03-27T08:07:18', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b1edd44-c9f3-405a-8a62-4ac8d78c658d' User entered '27 Mar 2021 08:07:18'	System	27 Mar 2021 15:07:20
	System	27 Mar 2021 15:07:20

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-05T12:16:39', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd0d28e05-c43c-4242-9220-312da573a07c' User entered 'No (N)'	System	05 Apr 2021 19:16:50
	System	05 Apr 2021 19:16:50

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-05T12:16:41', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd0d28e05-c43c-4242-9220-312da573a07c' User entered 'No (N)'	System	05 Apr 2021 19:16:50
	System	05 Apr 2021 19:16:50

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-05T12:16:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'd0d28e05-c43c-4242-9220-312da573a07c' User entered '05 Apr 2021 12:16:45'	System	05 Apr 2021 19:16:50
	System	05 Apr 2021 19:16:50

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:06:40', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered 'Yes (Y)'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:06:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered 'No (N)'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:06:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered 'No (N)'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:07:00', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered 'Yes (Y)'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Please 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:07:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-10T05:07:19', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '6b9ccd91-afdb-4db8-9d6f-638f6ba0f048'	System	10 Apr 2021 12:07:27
User entered '10 Apr 2021 05:07:19'	System	10 Apr 2021 12:07:27

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-18T08:51:47', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcdaf9c1-9106-49b0-baa0-6c18bc2c7ef6'	System	18 Apr 2021 15:51:54
User entered 'No (N)'	System	18 Apr 2021 15:51:54

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-18T08:51:49', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcdaf9c1-9106-49b0-baa0-6c18bc2c7ef6'	System	18 Apr 2021 15:51:54
User entered 'No (N)'	System	18 Apr 2021 15:51:54

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-18T08:51:51', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'dcdaf9c1-9106-49b0-baa0-6c18bc2c7ef6' User entered '18 Apr 2021 08:51:51'	System	18 Apr 2021 15:51:54
	System	18 Apr 2021 15:51:54

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-24T07:42:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '942126b3-f4a0-4750-885c-49b2879f7417' User entered 'No (N)'	System	24 Apr 2021 14:42:49
	System	24 Apr 2021 14:42:49

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-24T07:42:44', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '942126b3-f4a0-4750-885c-49b2879f7417' User entered 'No (N)'	System	24 Apr 2021 14:42:49

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-04-24T07:42:47', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '942126b3-f4a0-4750-885c-49b2879f7417' User entered '24 Apr 2021 07:42:47'	System	24 Apr 2021 14:42:49
	System	24 Apr 2021 14:42:49

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-05-02T08:32:43', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e4738568-ad0f-4e30-b8d6-59629e08efbf'	System	02 May 2021 15:33:00
User entered 'No (N)'	System	02 May 2021 15:33:00

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

Have you been exposed to someone with 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 (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-05-02T08:32:45', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e4738568-ad0f-4e30-b8d6-59629e08efbf'	System	02 May 2021 15:33:00
User entered 'No (N)'	System	02 May 2021 15:33:00

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-05-02T08:32:55', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: 'e4738568-ad0f-4e30-b8d6-59629e08efbf'	System	02 May 2021 15:33:00
User entered '02 May 2021 08:32:55'	System	02 May 2021 15:33:00

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:59:52

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:59:52

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:59:52

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:59:52

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:59:52

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:59:52

US3162068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:59:52
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:59:52

US3162068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:48

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 18:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-27T08:02:10', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '743575b1-f168-4c39-b18d-bb4711c57083'	System	27 Feb 2021 16:02:16
User entered 'No (N)'	System	27 Feb 2021 16:02:16

US3162068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (30B84EC8-3400-44EB-824C-BCCF68385828)', Time: '2021-02-27T08:02:14', User OID: 'PatientReportedOutcome (US3162068)', ODM File OID: '743575b1-f168-4c39-b18d-bb4711c57083' User entered '27 Feb 2021 08:02:14'	System	27 Feb 2021 16:02:16
	System	27 Feb 2021 16:02:16

US3162068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:48:58

US3162068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 16:48:58

US3162068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 16:48:58

US3162068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:48:58

US3162068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:49:04

US3162068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:10:47
User entered 'I'	System	03 Nov 2020 16:49:04

US3162068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:21:02

US3162068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '3 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:21:02

US3162068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:21:02

US3162068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:21:02

US3162068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	04 Dec 2020 18:21:08

US3162068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User entered 'I'	System	04 Dec 2020 18:21:08

US3162068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 16:49:27

US3162068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '31 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 16:49:27

US3162068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 16:49:27

US3162068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 16:49:27

US3162068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	05 Jan 2021 16:49:35

US3162068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User entered 'I'	System	05 Jan 2021 16:49:35

US3162068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 20:27:23

US3162068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '1 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 20:27:23

US3162068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 20:27:23

US3162068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 20:27:23

US3162068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 20:27:30

US3162068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:42:38
User entered 'I'	System	02 Feb 2021 20:27:30

US3162068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17MAR2021 however, the data on the Immunogenicity form in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 10:51:11
Query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17MAR2021 however, the data on the Immunogenicity form in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'RECONCILED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:36
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17MAR2021 however, the data on the Immunogenicity form in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:31:14
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 17:59:49

US3162068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '17 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 17:59:49

US3162068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[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 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 17:59:49

US3162068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered 'VISIT4'	System	18 Mar 2021 17:59:49

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered empty.	System	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered empty.	System	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered empty.	System	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered empty.	System	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered empty.	System	30 Mar 2021 03:42:52

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32

US3162068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32

US3162068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 18:00:02

US3162068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 18:00:02

US3162068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 18:00:27

US3162068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '17 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 18:00:27

US3162068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '10:39'	Tiffany Williams (b) (4) (b) (4)	18 Mar 2021 18:00:27

US3162068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered '17 Mar 2021 10:39'	System	18 Mar 2021 18:00:27

US3162068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 19:56:31

US3162068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:00:32
User entered 'I'	System	18 Feb 2021 19:56:31

US3162068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 17:13:24

US3162068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

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 22:59:56
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 17:13:24

US3162068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[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 22:59:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Apr 2021 17:13:24

US3162068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 17:13:24

US3162068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 17:14:24

US3162068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 17:14:24

US3162068

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:02:47

US3162068

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:02:47

US3162068

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:02:47

US3162068

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:02:47

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '0'	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 20:54:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:11:22

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 20:54:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:11:22

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '1'	System	22 Jan 2021 20:03:40

US3162068

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'I'	System	22 Jan 2021 20:03:40

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '70' in	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '185' lb	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '26.60024'	System	22 Jan 2021 20:12:38
DataPoint set to visible.	System	22 Jan 2021 20:03:40

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '70' in	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '185' lb	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '26.60024'	System	22 Jan 2021 20:12:38
DataPoint set to visible.	System	22 Jan 2021 20:03:40

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:25'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '20 Jan 2021 11:25'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '98.7' F	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '82'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'bpm'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '16'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'breaths/min'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '122'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'mmHg'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '85'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'mmHg'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '70' in	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '185' lb	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '26.60024'	System	22 Jan 2021 20:12:38
DataPoint set to visible.	System	22 Jan 2021 20:03:40

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '12:33'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '20 Jan 2021 12:33'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '99.2' F	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '62'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'bpm'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '18'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'breaths/min'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '120'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'mmHg'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '88'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:12:38

US3162068

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'mmHg'	System	22 Jan 2021 20:12:38

US3162068

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:00

US3162068

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:00

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 14:30:23
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered with 'corrected' (Site from System).	Judith Kirstein (b) (4) (b) (4)	28 Jan 2021 07:13:16
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	22 Jan 2021 20:13:46
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'mRNA-1273'	System	22 Jan 2021 20:13:46
DataPoint set to visible.	System	22 Jan 2021 20:03:40

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:58'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '20 Jan 2021 11:58'	System	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 20:55:39
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	13 Mar 2021 20:55:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'ONCE'	System	22 Jan 2021 20:13:46

US3162068

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 20:13:46

US3162068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:30

US3162068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:30

US3162068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:30'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:30

US3162068

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '20 Jan 2021 11:30'	System	22 Jan 2021 20:15:30

US3162068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:57

US3162068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '20 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:57

US3162068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '11:35'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:15:57

US3162068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered '20 Jan 2021 11:35'	System	22 Jan 2021 20:15:57

US3162068

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Jan 2021 20:16:03

US3162068

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:18
User entered 'I'	System	22 Jan 2021 20:16:03

US3162068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	30 Jan 2021 18:59:04
	(b) (4)	

US3162068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered '27 Jan 2021'	Tiffany Williams (b) (4)	30 Jan 2021 18:59:04
	(b) (4)	

US3162068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	30 Jan 2021 18:59:04
	(b) (4)	

US3162068

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	30 Jan 2021 18:59:04
	(b) (4)	

US3162068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	30 Jan 2021 18:59:38
	(b) (4)	

US3162068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User entered '1'	System	30 Jan 2021 18:59:38

US3162068

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:42
User entered 'I'	System	30 Jan 2021 18:59:38
DataPoint set to visible.	System	30 Jan 2021 18:59:38

US3162068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 19:59:25
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '18 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 19:59:25
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	18 Feb 2021 19:59:25
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'OLD29'	System	18 Feb 2021 19:59:25

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '18 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '11:20'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered '18 Feb 2021 11:20'	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '97.7' F	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '79'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'bpm'	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '12'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'breaths/min'	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '122'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'mmHg'	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '68'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'mmHg'	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '12:25' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered '18 Feb 2021 12:25'	System	25 Feb 2021 05:51:56
User entered empty.	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 20:01:17
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'bpm'	System	25 Feb 2021 05:51:56
User entered empty.	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'breaths/min'	System	25 Feb 2021 05:51:56
User entered empty.	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'mmHg'	System	25 Feb 2021 05:51:56
User entered empty.	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 05:51:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'mmHg'	System	25 Feb 2021 05:51:56
User entered empty.	System	18 Feb 2021 20:01:17

US3162068

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 20:02:48
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '18 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 20:02:48
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:50
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Feb 2021 20:01:50
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:50

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'mRNA-1273'	System	18 Feb 2021 20:01:50
DataPoint set to visible.	System	30 Jan 2021 18:59:38

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '18 Feb 2021'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:50
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '11:50'	Tiffany Williams (b) (4)	18 Feb 2021 20:01:50
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered '18 Feb 2021 11:50'	System	18 Feb 2021 20:01:50

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 06:23:18
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'PER SOURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:02:13
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	18 Feb 2021 20:01:50
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	18 Feb 2021 20:01:50

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'ONCE'	System	18 Feb 2021 20:01:50

US3162068

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 20:01:50

US3162068

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Feb 2021 20:02:22
	(b) (4)	

US3162068

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:34
User entered 'I'	System	18 Feb 2021 20:02:22

US3162068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:25:40

US3162068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:25:40

US3162068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:25:40

US3162068

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:25:40

US3162068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:25:47

US3162068

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:27
User entered 'I'	System	01 Mar 2021 17:25:47

US3162068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	18 Mar 2021 18:37:06
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '17 Mar 2021'	Tiffany Williams (b) (4)	18 Mar 2021 18:37:06
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	18 Mar 2021 18:37:06
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered 'OLD57'	System	18 Mar 2021 18:37:06

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:37:38

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:37:38

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:37:38

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:37:38

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:37:38
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:37:38

US3162068

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

US3162068

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	18 Mar 2021 18:38:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:38:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	18 Mar 2021 18:38:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:38:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	18 Mar 2021 18:38:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	18 Mar 2021 18:38:53

US3162068

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:28:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:22
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 173, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		01 Apr 2021 05:26:48
Query 'Per DM CLR: Per Safety Follow Up Diary Day 173, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'No changes in health. Was reporting getting first dose of OL vaccine' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	26 Mar 2021 03:20:55
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 173, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 01:56:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:23:49
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:28

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User closed query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:11:17
Query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' answered with 'Not known' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	14 Oct 2020 19:00:06
User opened query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:34:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:07:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:07:46
Data point term sent to Coder	System	28 Sep 2020 16:25:49
User entered 'Mid abdominal pain'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User entered empty.	System	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '23 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User entered empty.	System	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'None (NONE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[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 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User entered '0'	System	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:28
User entered '0'	System	28 Sep 2020 16:25:01

US3162068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous tissue ulcerations, PT: Skin ulcer, LLT: Foot ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:30:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:30:35
Data point term sent to Coder	System	10 Apr 2021 18:44:43
User entered 'Right great toe ulcer'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '1 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User entered empty.	System	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered '7 Apr 2021'	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User entered empty.	System	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	10 Apr 2021 18:43:46
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[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 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:43:46

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User entered '0'	System	10 Apr 2021 18:43:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:30
User entered 'I'	System	10 Apr 2021 18:43:46

US3162068

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:30

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:51:32
User entered		12 Apr 2021 14:51:28
'USA-US074-2021-mRNA-1273-P301000021'		
User entered 'New'		12 Apr 2021 14:51:28

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis of the foot - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:24:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:24:33
Data point term sent to Coder	System	10 Apr 2021 18:51:45
User entered 'osteomyelitis right great toe'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered '29 Mar 2021'	Judith Kirstein (b) (4)	10 Apr 2021 18:51:20
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Event end date is 07APR2021, when the toe was removed.' (Site from Safety).	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	23 Apr 2021 13:34:42 22 Apr 2021 21:36:32
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		19 Apr 2021 12:08:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
User entered '7 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	10 Apr 2021 18:51:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		12 Apr 2021 22:19:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		12 Apr 2021 22:19:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Apr 2021 18:51:20
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '7 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '10 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	12 Apr 2021 22:19:06
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide antibiotic treatment details given for the event osteomyelitis right great toe. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 20:23:36
Query 'PV Query: Please provide antibiotic treatment details given for the event osteomyelitis right great toe. ' answered with 'see con meds' (Site from Safety).	Judith Kirstein (b) (4)	22 Apr 2021 21:33:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User opened query 'PV Query: Please provide antibiotic treatment details given for the event osteomyelitis right great toe. ' (Site from Safety).		19 Apr 2021 12:08:26
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered 'I'	Judith Kirstein (b) (4)	10 Apr 2021 18:51:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:34:51
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'Updated' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:36:48
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).		19 Apr 2021 12:08:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:51:20

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User closed query 'PV Query: please confirm the dates of hemoglobin, hematocrit, erythrocyte sedimentation rate, c-reactive protein, bone biopsy, and pathology results ' (Site from Safety). Signature has been broken.	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 13:57:49 29 Apr 2021 16:45:33
User entered 'SUBJECT DEVELOPED ULCER ON PLANTAR SURFACE OF RIGHT GREAT TOE AND CELLULITIS, WHICH FAILED OUTPATIENT MANAGEMENT AND CAUSED OSTEOMYELITIS WHICH LED TO THE TOE BEING AMPUTATED ON 07APR2021. IN THE HOSPITAL, SUBJECT WAS TREATED WITH IV VANCOMYCIN, CEFTRIAZONE AND METRONIDAZOLE. HE WAS SENT HOME ON IV CEFTRIAZONE AND ORAL METRONIDAZOLE TO COMPLETE A 14 DAY COURSE. PATHOLOGY OF HIS AMPUTATED TOE SHOWED OSTEOMYELITIS BUT HIS METATARSAL BONE BIOPSY done 07apr2021 SHOWED NO INFECTION (reported 13apr2021.) DURING THE HOSPITAL STAY, HE EXPERIENCED CONSTIPATION, INTERMITTENT ELEVATIONS OF HIS BLOOD PRESSURE BETWEEN 08APR AND 10APR, MILD NONSPECIFIC ANEMIA, WITH HEMOGLOBIN 11.7 G/DL (NORMAL 14-18) AND HEMATOCRIT 34.5 G/DL (NORMAL 42-52), ELEVATIONS OF ERYTHROCYTE SEDIMENTATION RATE (46 MM/HOUR WITH NORMAL BEING 0-20) AND C-REACTIVE PROTEIN (64 MG/L, WITH NORMAL BEING <7.4) , AND TRANSIENT ELEVATED BLOOD UREA NITROGEN 27 MG/DL ON 07APR, DECLINING TO 18 ON 09APR (NORMAL <18).'	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 16:45:33
reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: please confirm the dates of hemoglobin, hematocrit, erythrocyte sedimentation rate, c-reactive protein, bone biopsy, and pathology results ' answered with 'Labs were all on 07APR2021, bone biopsy was on 07APR2021 and pathology results were on 13APR2021' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	29 Apr 2021 16:43:24
User opened query 'PV Query: please confirm the dates of hemoglobin, hematocrit, erythrocyte sedimentation rate, c-reactive protein, bone biopsy, and pathology results ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 17:21:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT DEVELOPED ULCER ON PLANTAR SURFACE OF RIGHT GREAT TOE and cellulitis, WHICH FAILED OUTPATIENT MANAGEMENT AND CAUSED OSTEOMYELITIS which LED TO THE TOE BEING AMPUTATED ON 07APR2021. IN THE HOSPITAL, SUBJECT WAS TREATED WITH IV VANCOMYCIN, CEFTRIAXONE AND METRONIDAZOLE. HE WAS SENT HOME ON IV CEFTRIAXONE AND ORAL METRONIDAZOLE TO COMPLETE A 14 DAY COURSE. PATHOLOGY OF HIS AMPUTATED TOE SHOWED OSTEOMYELITIS but HIS METATARSAL BONE BIOPSY SHOWED NO INFECTION. DURING THE HOSPITAL STAY, HE EXPERIENCED CONSTIPATION, INTERMITTENT ELEVATIONS OF HIS BLOOD PRESSURE BETWEEN 08APR AND 10APR, MILD NONSPECIFIC ANEMIA, WITH HEMOGLOBIN 11.7 G/DL (NORMAL 14-18) AND HEMATOCRIT 34.5 G/DL (NORMAL 42-52), ELEVATIONS OF ERYTHROCYTE SEDIMENTATION RATE (46 MM/HOUR WITH NORMAL BEING 0-20) AND C-REACTIVE PROTEIN (64 MG/L, WITH NORMAL BEING <7.4) , AND TRANSIENT ELEVATED BLOOD UREA NITROGEN 27 MG/DL ON 07APR, DECLINING TO 18 ON 09APR (NORMAL <18).' <p>reason for change: Data Entry Error</p> <p>User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).</p> <p>User closed query 'PV Query: Please provide details how subject developed ulcer of right great toe. ' (Site from Safety).</p> <p>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).</p>	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:35:59
	(b) (4), (b) (6)	21 Apr 2021 17:31:24
		21 Apr 2021 17:31:23
		21 Apr 2021 17:31:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

1995 of 3072

US3162068

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:21
User entered 'SUBJECT DEVELOPED ULCER ON PLANTAR SURFACE OF RIGHT GREAT TOE WHICH FAILED OUTPATIENT MANAGEMENT AND CAUSED OSTEOMYELITIS AND LED TO THE TOE BEING AMPUTATED ON 07APR2021. IN THE HOSPITAL, SUBJECT WAS TREATED WITH IV VANCOMYCIN, CEFTRIAXONE AND METRONIDAZOLE. HE WAS SENT HOME ON IV CEFTRIAXONE AND ORAL METRONIDAZOLE TO COMPLETE A 14 DAY COURSE. Pathology of his amputated toe showed osteomyelitis HIS METATARSAL BONE BIOPSY SHOWED NO INFECTION. DURING THE HOSPITAL STAY, HE EXPERIENCED CONSTIPATION, INTERMITTENT ELEVATIONS OF HIS BLOOD PRESSURE BETWEEN 08APR AND 10APR, MILD NONSPECIFIC ANEMIA, WITH HEMOGLOBIN 11.7 G/DL (NORMAL 14-18) AND HEMATOCRIT 34.5 G/DL (NORMAL 42-52), ELEVATIONS OF ERYTHROCYTE SEDIMENTATION RATE (46 MM/HOUR WITH NORMAL BEING 0-20) AND C-REACTIVE PROTEIN (64 MG/L, WITH NORMAL BEING <7.4) , AND TRANSIENT ELEVATED BLOOD UREA NITROGEN 27 MG/DL ON 07APR, DECLINING TO 18 ON 09APR (NORMAL <18)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 04:53:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Narrative updated' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 04:51:46
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 04:51:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT DEVELOPED ULCER on plantar surface OF RIGHT GREAT TOE WHICH failed outpatient management and CAUSED OSTEOMYELITIS AND LED TO THE TOE BEING AMPUTATED ON 07APR2021. In the hospital, subject was treated with IV vancomycin, ceftriaxone and metronidazole. He was sent home on IV ceftriaxone and oral metronidazole to complete a 14 day course. His metatarsal bone biopsy showed no infection. During the hospital stay, he experienced constipation, intermittent elevations of his blood pressure between 08APR and 10APR, mild nonspecific anemia, with hemoglobin 11.7 g/dL (normal 14-18) and hematocrit 34.5 g/dL (normal 42-52), elevations of erythrocyte sedimentation rate (46 mm/hour with normal being 0-20) and C-reactive protein (64 mg/L, with normal being <7.4) , and transient elevated blood urea nitrogen 27 mg/dL on 07APR, declining to 18 on 09APR (normal <18)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 04:51:08
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 '07APR2021: SARS/Influenza A&B/multiplex NAA. All were negative' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:48:53
Query 'PV Query: Please provide details how subject developed ulcer of right great toe. ' answered with 'Subject has peripheral neuropathy causing lack of sensation on the plantar surface of both great toes.' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:47:12
User opened query 'PV Query: Please provide details how subject developed ulcer of right great toe. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:09:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		19 Apr 2021 12:08:56

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:08:49
User signature succeeded.	Judith Kirstein (b) (4)	14 Apr 2021 18:15:51
	(b) (4)	
User entered 'Subject developed ulcer of right great toe which caused osteomyelitis and led to hospitalization and the toe being amputated on 07APR2021. IV antibiotics are continuing.'	Judith Kirstein (b) (4)	10 Apr 2021 18:51:20
	(b) (4)	

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Apr 2021 18:51:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:08:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:08:44
Data point term sent to Coder	System	20 Apr 2021 17:07:33
User entered 'Constipation'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User entered empty.	System	20 Apr 2021 17:07:22

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '11 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User entered empty.	System	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:07:22

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User entered '0'	System	20 Apr 2021 17:07:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:43
User entered 'I'	System	20 Apr 2021 17:07:22

US3162068

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:54:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as SOC: Investigations, HLG: Renal and urinary tract investigations and urinalyses, HLT: Renal function analyses, PT: Blood urea increased, LLT: Blood urea nitrogen increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:28:09
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 12:28:09
Data point term sent to Coder	System	20 Apr 2021 17:11:52
User entered 'Transient elevation of blood urea nitrogen'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User entered empty.	System	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User entered empty.	System	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[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 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User entered '0'	System	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
User entered 'I'	System	20 Apr 2021 17:11:18

US3162068

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:55:04

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:16:01
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 12:16:01
Data point term sent to Coder	System	20 Apr 2021 17:13:55
User entered 'Mild non-specific anemia'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User entered empty.	System	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User entered empty.	System	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[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 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User entered '0'	System	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:04
User entered 'I'	System	20 Apr 2021 17:12:59

US3162068

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:55:04

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 12:55:13

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Blood pressure increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:51:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:51:49
Data point term sent to Coder	System	20 Apr 2021 17:14:57
User entered 'Intermittent elevation of blood pressure'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User entered empty.	System	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User entered empty.	System	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

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 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User entered '0'	System	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13
User entered 'I'	System	20 Apr 2021 17:14:52

US3162068

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:13

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:19:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:19:50
Data point term sent to Coder	System	22 Apr 2021 21:32:41
User entered 'cellulitis right great toe'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered '22 Mar 2021'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User entered empty.	System	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:33
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:33
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User entered '22 Apr 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User entered empty.	System	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	22 Apr 2021 21:31:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:33
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:59:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User entered '0'	System	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50
User entered 'I'	System	22 Apr 2021 21:31:47

US3162068

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:28:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:28:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:48

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:04:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 04:04:08
Data point term sent to Coder	System	07 Aug 2020 04:02:30
User entered 'metoprolol'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	18 Apr 2021 05:22:10
User entered '12.5' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Apr 2021 05:22:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '25'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	18 Apr 2021 05:22:10
User entered 'twice daily (BID)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	18 Apr 2021 05:22:10
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 12:14:02
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 04:02:14
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Apr 2021 05:22:10
User entered '1'	System	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:02:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
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: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 04:04:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 04:04:09
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 04:03:31
User entered 'benazepril'	Jared Bradshaw (b) (4)	07 Aug 2020 04:02:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '40'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 12:14:19
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 04:02:55
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:02:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 04:04:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 04:04:09
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 04:03:31
User entered 'simvastatin'	Jared Bradshaw (b) (4)	07 Aug 2020 04:03:26
	(b) (4)	

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 21:04:28
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	13 Sep 2020 23:31:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:23:56
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '80'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 12:14:27
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 04:03:26
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:03:26

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 03:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 03:51:49
Data point term sent to Coder	System	20 Apr 2021 03:51:09
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:50:14
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:50:14
User entered 'HYDROCHLORoTHIAZIDE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:50:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:56:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:56:14
Data point term sent to Coder	System	07 Aug 2020 04:04:31
User entered 'hydrochlorithiazide'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '25'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
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 12:14:35
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 04:03:55
User entered 'un UNK 2000'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 04:03:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 01:02:07
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 08:01:16
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Jan 2021 08:01:16
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	21 Jan 2021 03:00:04
User entered 'voltaren gel'	Jessica Fisher (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jessica Fisher (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'tendinitis left shoulder'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '2'	Jessica Fisher (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'g (g)'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'as needed (PRN)'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jessica Fisher (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Topical (TOPICAL)'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'un Jun 2020'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered '0'	Jessica Fisher (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'Yes (Y)'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered empty.	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jessica Fisher (b) (4) (b) (4)	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 02:59:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:49:43
Data point term sent to Coder	System	22 Apr 2021 21:38:46
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:37:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:54:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:54:50
Data point term sent to Coder	System	10 Apr 2021 18:56:46
Data point term sent to Coder	System	10 Apr 2021 18:55:46
User entered 'bactrim ds (sulfamethoxazole/trimethoprim)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:37:52
User entered 'cellulitis RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:37:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'RIGHT GREAT TOE ULCER' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:56:26
User entered 'Ulcer right great toe'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered '800/160'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'twice daily (BID)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered empty.	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered '29 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered '0'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered '7 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:55
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Apr 2021 18:55:31

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:21:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:21:36
Data point term sent to Coder	System	17 Apr 2021 00:20:25
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Influenza prevention'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0.5'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'cc'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '30 Oct 2020'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '30 Oct 2020'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User entered empty.	System	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User entered empty.	System	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:04
User entered empty.	System	17 Apr 2021 00:19:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:22:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:22:51
Data point term sent to Coder	System	17 Apr 2021 00:21:26
User entered 'Omeprazole'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6) (b) (4)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '40'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Apr 2021 00:20:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:22:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:22:51
Data point term sent to Coder	System	17 Apr 2021 00:21:26
User entered 'Magnesium'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Nutritional supplement'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '600'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Apr 2021 00:21:19

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:23:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:23:36
Data point term sent to Coder	System	17 Apr 2021 00:22:41
User entered 'Albuterol'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Mild Asthma'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '180'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'ug (ug)'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:24:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:24:37
Data point term sent to Coder	System	17 Apr 2021 00:23:41
User entered 'Flovent'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Mild asthma'	(b) (4), (b) (6) (b) (4)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '220'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'ug (ug)'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:22:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUNISOLIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:45:29
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 14:45:29
Data point term sent to Coder	System	17 Apr 2021 00:24:42
User entered 'Flunisolide .025% nasal spray'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Environmental Allergies'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '50'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'ug (ug)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2014'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:24:00

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:54:39
Data point term sent to Coder	System	22 Apr 2021 21:38:46
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:38:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:30:39
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 13:30:39
Data point term sent to Coder	System	17 Apr 2021 00:25:42
User entered 'Ceftriaxone'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'celluLITIS RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:38:31
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '2000'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '07 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:03:30
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:03:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:03:30
User entered '22 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:03:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Apr 2021 00:25:18

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:19:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:19:46
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 21:39:47
Coding entries removed.	Judith Kirstein (b) (4)	22 Apr 2021 21:38:48
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:53:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:53:30
	(b) (4)	
Data point term sent to Coder	System	17 Apr 2021 00:26:43
User entered 'Metronidazole'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'celluLITIS RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:38:48
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '500'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'three times daily (TID)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:03:56
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:03:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:03:56
User entered '22 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:03:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Apr 2021 00:26:03

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:27:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Apr 2021 00:27:37
Data point term sent to Coder	System	17 Apr 2021 00:26:43
User entered 'Bisacodyl'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Constipation'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'ug (ug)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Apr 2021 00:26:39

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
Data point term sent to Coder	System	20 Apr 2021 17:17:00
User entered 'Meloxicam'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '15'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '11 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:16:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
Data point term sent to Coder	System	20 Apr 2021 17:18:02
User entered 'Meloxicam'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '15'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '12 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:04:18
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:04:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	28 Apr 2021 22:27:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 22:04:18
User entered '21 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:04:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:17:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:33:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:33:43
Data point term sent to Coder	System	20 Apr 2021 17:19:03
User entered 'Miralax (polyethylene glycol)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Constipation'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '17'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'g (g)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:18:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:31:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:31:27
Data point term sent to Coder	System	20 Apr 2021 17:20:04
User entered 'Senokot (sennosides)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Constipation'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '17.2'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:19:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 07:15:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 07:15:11
Data point term sent to Coder	System	20 Apr 2021 17:21:06
User entered 'Vancomycin'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '2000'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:20:49

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:50:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:50:46
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 21:40:48
Coding entries removed.	Judith Kirstein (b) (4)	22 Apr 2021 21:39:47
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 07:15:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 07:15:11
	(b) (4)	
Data point term sent to Coder	System	20 Apr 2021 17:22:06
User entered 'Vancomycin'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'celluLITIS RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:39:47
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '1500'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Every 12 hours'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:21:57

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:25:49
Data point term sent to Coder	System	20 Apr 2021 17:24:09
User entered 'Marcaine 0.5%'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prophylaxis against pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:23:30

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
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)	20 Apr 2021 21:11:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:11:32
Data point term sent to Coder	System	20 Apr 2021 17:25:10
User entered 'Lidocaine 1%'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prophylaxis against pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:24:37

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:26:43
Data point term sent to Coder	System	20 Apr 2021 17:26:11
User entered 'Normal saline flush'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent clot in intravenous line'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:25:16

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:26:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:26:41
Data point term sent to Coder	System	20 Apr 2021 17:26:11
User entered 'Acetaminophen'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '1000'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:06

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:27:35
Data point term sent to Coder	System	20 Apr 2021 17:27:15
User entered 'Acetaminophen'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '650'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:26:52

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:38:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:38:31
Data point term sent to Coder	System	20 Apr 2021 17:28:22
User entered '5% dextrose/0.45% saline IV fluid'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent dehydration'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '50'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Every hour'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:28:07

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:30:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:30:32
Data point term sent to Coder	System	20 Apr 2021 17:29:23
User entered 'Docusate'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Constipation'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '100'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:29:14

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:02:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:02:36
Data point term sent to Coder	System	20 Apr 2021 17:33:30
User entered 'Famotidine'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent Gastric hyperacidity'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '20'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:32:43

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
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)	20 Apr 2021 20:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:12:46
Data point term sent to Coder	System	20 Apr 2021 17:33:30
User entered 'Heparin'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent Thrombosis'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '5000'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'IU (IU)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:33:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:16:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:16:48
Data point term sent to Coder	System	20 Apr 2021 17:35:31
User entered 'Hydromorphone'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:34:44

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: RINGER'S SOLUTION [CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:39
Data point term sent to Coder	System	20 Apr 2021 17:36:32
User entered 'Lactate Ringer's IV solution'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent dehydration'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '125'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Every hour'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '8 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:35:34

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
Data point term sent to Coder	System	20 Apr 2021 17:36:33
User entered 'Melatonin'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent insomnia'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:36:29

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:54:37
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:21:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:21:48
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 21:40:48
Coding entries removed.	Judith Kirstein (b) (4)	22 Apr 2021 21:40:34
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:30:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:30:37
	(b) (4)	
Data point term sent to Coder	System	20 Apr 2021 17:38:35
User entered 'Metronidazole'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'celluLITIS RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:40:34
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '500'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Every 8 hours'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '10 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:37:45

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:40:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:40:38
Data point term sent to Coder	System	20 Apr 2021 17:39:38
User entered 'Hydrocodone/acetaminophen'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Pain from right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '5/325'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '9 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:39:28

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGER'S - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:40
Data point term sent to Coder	System	20 Apr 2021 17:41:41
User entered 'Lactated Ringers IV solution'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent dehydration during surgery'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '75'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Every hour'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:40:59

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
Data point term sent to Coder	System	20 Apr 2021 17:42:42
User entered 'Ketamine'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Anesthesia for right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '20'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:41:55

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:29:39
Data point term sent to Coder	System	20 Apr 2021 17:43:43
User entered 'Propofol'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Anesthesia for right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '50'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:42:51

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:29:39
Data point term sent to Coder	System	20 Apr 2021 17:44:45
User entered 'Propofol drip'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Anesthesia for right great toe amputation'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '300'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'continuous during operation'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:44:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:27:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:27:38
Data point term sent to Coder	System	20 Apr 2021 17:45:54
User entered 'Ondansetron'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent nausea during surgery'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '4'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:45:09

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IB, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:09:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:09:59
Data point term sent to Coder	System	20 Apr 2021 17:46:56
User entered 'Lidocaine'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Prevent arrhythmias during surgery'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '100'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 17:46:12

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
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)	20 Apr 2021 17:48:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:48:39
Data point term sent to Coder	System	20 Apr 2021 17:47:00
User entered 'Aspirin'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Cardiac protection'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '81'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'UN UNK 2010'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:46:50

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 01:55:40
Data point term sent to Coder	System	22 Apr 2021 21:41:49
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:41:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:08:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:08:51
Data point term sent to Coder	System	20 Apr 2021 17:49:01
User entered 'Cephalexin'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'celluLITIS RIGHT GREAT TOE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Apr 2021 21:41:35
User entered 'Osteomyelitis right great toe'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '500'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'four times daily (QID)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '1 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered '7 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:54:37
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:28:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 17:48:13

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:28:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:16:05
User closed query 'Per ETRTR, According to SAE, Osteomyelitis Right Great Toe, subject had a Concomitant procedure but no Concomitant procedure is entered. Please reconcile.' (Site from CRA).		20 Apr 2021 16:16:03
Query 'Per ETRTR, According to SAE, Osteomyelitis Right Great Toe, subject had a Concomitant procedure but no Concomitant procedure is entered. Please reconcile.' answered with 'con procedure log updated.' (Site from CRA).		19 Apr 2021 22:29:05
User entered 'Yes (Y)' reason for change: New Information		19 Apr 2021 22:24:59
User opened query 'Per ETRTR, According to SAE, Osteomyelitis Right Great Toe, subject had a Concomitant procedure but no Concomitant procedure is entered. Please reconcile.' (Site from CRA).		19 Apr 2021 04:03:17
User closed query 'Please review and confirm response and add procedure to EDC.' (Site from CRA).		17 Apr 2021 01:56:12
Query 'Please review and confirm response and add procedure to EDC.' answered with 'data entry error. No con procedure present in eSource.' (Site from CRA).		17 Apr 2021 00:28:26
User entered 'No (N)' reason for change: Data Entry Error		17 Apr 2021 00:27:29
User opened query 'Please review and confirm response and add procedure to EDC.' (Site from CRA).		16 Apr 2021 21:41:19
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	16 Apr 2021 00:14:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	16 Apr 2021 00:14:16

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:28:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 01:02:07
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	07 Aug 2020 04:01:33

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered '7 Apr 2021'	(b)(4) (b)(6)	19 Apr 2021 22:25:55

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered 'Right great toe amputation'	(b)(4) (b)(6)	19 Apr 2021 22:25:55

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	19 Apr 2021 22:25:55

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 22:25:55

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:28:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered '7 Apr 2021'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:58:37

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:28:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered 'right first metatarsal bone biopsy'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:58:37

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:28:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:58:37

US3162068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:28:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:32
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:58:37

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
User entered '12/Apr/2021 10:52'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'I'		12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'		12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
User entered '13/Apr/2021 08:56'	System	13 Apr 2021 12:56:31

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:31:47
DataPoint Verified.		20 Apr 2021 18:11:38
User entered 'I'		13 Apr 2021 12:56:31

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered '21/Apr/2021 13:31'	System	21 Apr 2021 17:31:44

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:31:47
User entered 'I'		21 Apr 2021 17:31:44

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:59:56
	(b) (4)	
User entered '23/Apr/2021 09:35'	System	23 Apr 2021 13:35:10

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:28:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 13:35:10

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:10
User entered 'USA-US074-2021-MRNA-1273-P301000021'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Yes (Y)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'No (N)'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Judith'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'Kirstein'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'BANNING'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered 'CA'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.		12 Apr 2021 14:52:14
User entered '92220'	System	12 Apr 2021 14:51:28

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:59:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:11:38
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:52:14
User entered 'US'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 13:28:35
User entered '4'	System	23 Apr 2021 13:35:10
User entered '3'	System	21 Apr 2021 17:31:44
User entered '2'	System	13 Apr 2021 12:56:31
User entered '1'	System	12 Apr 2021 14:52:02

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:28:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	30 Apr 2021 15:29:31
	(b) (4)	
User entered '30/Apr/2021 06:28'	System	30 Apr 2021 13:28:35

US3162068

Folder: SAE USA-US074-2021-MRNA-1273-P301000021

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:28:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	30 Apr 2021 15:29:31
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 13:28:35