

US3162238 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:31:17

All time stamps listed in this document are displayed in GMT

US3162238

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:45:47

Generated On: 09 Jun 2021 15:31:17

Participant ID

US3162238

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

US3162238

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	SCRN

US3162238

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Date of Informed Consent (*dd MMM yyyy*) 15 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify

Was this participant screened previously?

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

If Yes, previous participant number

Enrollment Trigger 1

US3162238

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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 04:45:54

Generated On: 09 Jun 2021 15:31:17

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

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)	

US3162238

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162238

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3162238

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	OBESITY
Start date (dd MMM yyyy)	UN JAN 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3162238

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Mar 2021 19:56:55

Generated On: 09 Jun 2021 15:31:17

Condition	RECURRENT TONSILLITIS
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3162238

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:21 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:21
Height (<i>xxx.x</i>)	170.2 cm
Weight (<i>xxx.x</i>)	90.3 kg
BMI (<i>xxx.x</i>)	31.17229 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 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Date of assessment (dd MMM yyyy) 15 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2013

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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 04:45:54

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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 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 146041

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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)	15 SEP 2020
Time of assessment (00:00-23:59)	15:21 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:21
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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)	15 SEP 2020
Time of assessment (00:00-23:59)	17:39 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 17:39
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 16:58 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 16:58

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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

Collection date (dd MMM yyyy)	15 SEP 2020
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Collection time (00:00-23:59)	16:18 (24 HR)
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Collection date and time (derived)	15 SEP 2020 16:18
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US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:21	15 SEP 2020 16:21
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:44

PC Open Date & Time

15 SEP 2020 17:18

PC Close Date & Time

15 SEP 2020 19:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	16 SEP 2020 10:12
PC Open Date & Time	15 SEP 2020 20:43
PC Close Date & Time	16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

18 SEP 2020 12:47

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 13:40

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

98.3 °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

21 SEP 2020 12:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

15 SEP 2020 17:39

PC Open Date & Time

15 SEP 2020 17:18

PC Close Date & Time

15 SEP 2020 19:48

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 20:43

PC Close Date & Time

16 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

16 SEP 2020 12:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

17 SEP 2020 12:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

18 SEP 2020 12:47

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

20 SEP 2020 13:41

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

21 SEP 2020 12:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 17:40
PC Open Date & Time	15 SEP 2020 17:18
PC Close Date & Time	15 SEP 2020 19:48

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 20:43

PC Close Date & Time

16 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

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EAB) (1725)

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2349

EAB) (1725)

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2349

EAB) (1725)

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:48
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 ☒

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:41
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 ☒

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:32
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3162238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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)	13 OCT 2020
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:33
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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)	13 OCT 2020
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:56
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 15:08 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 15:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3162238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

14:41 (24 HR)

Collection date and time (derived)

13 OCT 2020 14:41

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:50	13 OCT 2020 14:50
Nasopharyngeal Swab 2	No		

US3162238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 15:56

PC Open Date & Time

13 OCT 2020 15:28

PC Close Date & Time

13 OCT 2020 17:58

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 97.7 °F

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

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

PC Time Stamp	13 OCT 2020 19:19
PC Open Date & Time	13 OCT 2020 18:53
PC Close Date & Time	14 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 13:09

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

96.0 °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

15 OCT 2020 13:34

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 OCT 2020 12:28

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

97.8 °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

17 OCT 2020 13:22

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 6

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

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

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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

18 OCT 2020 12:10

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 7

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 19:21

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

13 OCT 2020 15:56

PC Open Date & Time

13 OCT 2020 15:28

PC Close Date & Time

13 OCT 2020 17:58

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

13 OCT 2020 19:20

PC Open Date & Time

13 OCT 2020 18:53

PC Close Date & Time

14 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

14 OCT 2020 13:09

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

15 OCT 2020 13:35

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

16 OCT 2020 12:29

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

17 OCT 2020 13:22

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

18 OCT 2020 12:10

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

19 OCT 2020 19:21

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 15:57
PC Open Date & Time	13 OCT 2020 15:28
PC Close Date & Time	13 OCT 2020 17:58

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 19:20
PC Open Date & Time	13 OCT 2020 18:53
PC Close Date & Time	14 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 ☒

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 13:10
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 13:35
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

		Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 12:29	
PC Open Date & Time	16 OCT 2020 12:00	
PC Close Date & Time	17 OCT 2020 11:59	

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 ☒

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 13:23
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 12:11
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 ☒

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 19:21
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3162238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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

Visit date (dd MMM yyyy)	10 NOV 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 09:15
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

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.

US3162238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 NOV 2020

Collection time (00:00-23:59) 10:09 (24 HR)

Collection date and time (derived) 10 NOV 2020 10:09

US3162238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:54

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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	16 NOV 2020 11:13:02
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 00:02:17
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 11:25:48

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 82
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 DEC 2020 21:23:51
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 11:47:52
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 04:02:53
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 02:33:39

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 07:27:38

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

07 JAN 2021 16:33:02

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

14 JAN 2021 00:35:01

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 00:02:02

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

28 JAN 2021 10:25:54

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

04 FEB 2021 00:01:39

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 13:22:45

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

18 FEB 2021 02:37:26

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

25 FEB 2021 00:01:50

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 00:57:28

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 MAR 2021 00:02:31
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

18 MAR 2021 05:32:45

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 MAR 2021 08:03:47
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 00:02:12

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

08 APR 2021 07:37:37

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

15 APR 2021 00:40:49

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

22 APR 2021 23:43:30

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 06:29:22
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 362

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

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

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

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

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

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

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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="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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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="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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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="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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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°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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 NOV 2022 00:01
Patient Cloud Close Date & Time	14 NOV 2022 23:59

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	17 NOV 2022 00:01
Patient Cloud Close Date & Time	21 NOV 2022 23:59

US3162238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:31:17

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		28 FEB 2021 15:15:54

US3162238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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

Visit date (dd MMM yyyy)	13 APR 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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US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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) _____

US3162238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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.

US3162238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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

Collection date (dd MMM yyyy)	13 APR 2021
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Collection time (00:00-23:59)	11:58 (24 HR)
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Collection date and time (derived)	13 APR 2021 11:58
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US3162238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162238

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:31:17

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"/>

US3162238

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:31:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3162238

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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

Visit date (dd MMM yyyy)	12 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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US3162238

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3162238

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Height	67 in
Weight	199 lb
BMI (xxx.x)	31.23298

US3162238

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Height	67 in
Weight	199 lb
BMI (xxx.x)	31.23298
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 11:35
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Height	67 in
Weight	199 lb
BMI (xxx.x)	31.23298
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)	12 JAN 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:05
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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.

US3162238

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 12:29 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 12:29

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

US3162238

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 JAN 2021

Collection time (00:00-23:59) 11:09 (24 HR)

Collection date and time (derived) 12 JAN 2021 11:09

US3162238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 JAN 2021

Collection time (00:00 - 23:59) 11:03

Collection Date and Time (derived) 12 JAN 2021 11:03

US3162238

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:26
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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)	11 FEB 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 11:18
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3162238

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:15:00

Generated On: 09 Jun 2021 15:31:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3162238

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 10:43

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

US3162238

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162238

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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) _____

US3162238

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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.

US3162238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

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

Collection date (dd MMM yyyy)	22 FEB 2021
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Collection time (00:00-23:59)	14:43 (24 HR)
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Collection date and time (derived)	22 FEB 2021 14:43
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US3162238

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

AEID	
Adverse event	SORE THROAT
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

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

Generated On: 09 Jun 2021 15:31:17

AEID	USA-US074-2021-MRNA-1273-P30 1000019
Adverse event	POST-OPERATIVE HYPOXIA
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)	25 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	26 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

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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	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	SUBJECT HAD PLANNED TONSILLECTOMY AND ADENOIDECTOMY ON 25FEB21 AND WAS NOTED TO BE HYPOXIC AFTER SURGERY, SO ADMITTED OVERNIGHT, DISCHARGED THE NEXT DAY 26FEB21
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (2)

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

AEID	
Adverse event	WORSENING OF OBSTRUCTIVE SLEEP APNEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 (3)

Generated On: 09 Jun 2021 15:31:17

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (4)

Generated On: 09 Jun 2021 15:31:17

AEID

Adverse event

WORSENING OF RECURRENT
TONSILLITIS

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)

01 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 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 (4)

Generated On: 09 Jun 2021 15:31:17

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

Generated On: 09 Jun 2021 15:31:17

AEID

Adverse event

PAIN DUE TO TONSILLECTOMY
AND ADENOIDECTOMY

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)

25 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 MAR 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 (5)

Generated On: 09 Jun 2021 15:31:17

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 (6)

Generated On: 09 Jun 2021 15:31:17

AEID	
Adverse event	DEVIATED NASAL SEPTUM
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)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:45:53

Generated On: 09 Jun 2021 15:31:17

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) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication RAMIPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication ATORVASTATIN

Prophylaxis Yes ☒
No ☐

Indication STROKE PREVENTION

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 (3)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 0.75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS

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)

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication ROPINAROLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication IPRATROPIUM
BROMIDE/ALBUTEROL
SULFATE INHALATION
SOLUTION

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 0.5/2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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 (8)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL 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 ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (9)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (9)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication TUMERIC

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (10)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (11)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

Name of Medication NORCO (HYDROCODONE
BITARTRATE/ACETAMINOPHEN
)

Prophylaxis Yes ☐
No ☒

Indication PAIN DUE TO TONSILLECTOMY
AND ADENOIDECTOMY

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q4H

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:27:43

Generated On: 09 Jun 2021 15:31:17

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:30:18

Generated On: 09 Jun 2021 15:31:17

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 21:30:18

Generated On: 09 Jun 2021 15:31:17

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 FEB 2021	BILATERAL TONSILLECTOMY	Adverse Event	
25 FEB 2021	BILATERAL ADENOIDECTOMY	Adverse Event	

US3162238

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:31:17

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

US3162238

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:31:17

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 ☐

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

SAEID	USA-US074-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

SAEID	USA-US074-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/MAR/2021 10:56
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

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

SAEID	USA-US074-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 23:15:07

Generated On: 09 Jun 2021 15:31:17

SAEID	USA-US074-2021-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/APR/2021 14:56
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

Audit

US3162238 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162238

Form: Participant Creation

Generated On: 09 Jun 2021 15:31:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:47
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:39:00
User entered 'US3162238'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:24:16

US3162238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:23
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:28

US3162238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:23
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:24:17

US3162238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:23
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:28

US3162238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'SCRN'	System	16 Sep 2020 19:22:28

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:24:18

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:22:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 19:22:51
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	16 Sep 2020 19:22:51
User entered '47' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:51
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:22:38
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	16 Sep 2020 19:22:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'YEARS'	System	16 Sep 2020 19:22:51
User entered empty.	System	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '47'	System	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered 'Female (F)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:41
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered '15 Sep 2020'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Sep 2020'	System	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2020'	System	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered 'Amendment 3 (3)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Sep 2020 21:33:22
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:38

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:48
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	17 Sep 2020 21:33:22
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	16 Sep 2020 00:37:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 22:24:17

US3162238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'I'	System	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:31:17

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:30:52
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:31:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:48
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:55

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:20:41
Data point term sent to Coder	System	16 Sep 2020 19:20:23
User entered 'hypertension'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2000'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2000'	System	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2000'	System	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:13

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:20:41
Data point term sent to Coder	System	16 Sep 2020 19:20:23
User entered 'TYPE 2 DIABETES'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2018'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2018'	System	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2018'	System	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:22

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
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)	16 Sep 2020 19:22:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:22:46
Data point term sent to Coder	System	16 Sep 2020 19:21:23
User entered 'Mild asthma'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		17 Sep 2020 21:28:29
User entered 'UN UNK 1974' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Sep 2020 21:28:29
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	16 Sep 2020 19:20:36
User entered 'un UNK 1973'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 1974'	System	17 Sep 2020 21:28:29
User entered 'Jan 1973'	System	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '1974'	System	17 Sep 2020 21:28:29
User entered '1973'	System	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:36

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:22:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:22:46
Data point term sent to Coder	System	16 Sep 2020 19:21:23
User entered 'RESTLESS LEG SYNDROME'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2018'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2018'	System	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2018'	System	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:20:47

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:45
Data point term sent to Coder	System	16 Sep 2020 19:22:26
User entered 'Seasonal allergies' reason for change:	Cynthia Kunakom (b) (4)	16 Sep 2020 19:22:01
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 19:21:25
User entered 'RESTLESS LEG SYNDROME'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'UN UNK 1975' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:01
User entered 'un UNK 2018'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 1975'	System	16 Sep 2020 19:22:01
User entered 'Jan 2018'	System	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '1975'	System	16 Sep 2020 19:22:01
User entered '2018'	System	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:21:17

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:44
Data point term sent to Coder	System	16 Sep 2020 19:22:26
User entered 'Uterine fibroids'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2012'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2013'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2012'	System	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2012'	System	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2013'	System	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2013'	System	16 Sep 2020 19:21:28

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:23:44
Data point term sent to Coder	System	16 Sep 2020 19:22:27
User entered 'obesity'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un Jan 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2020'	System	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2020'	System	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	16 Sep 2020 19:22:16

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Mar 2021 19:56:55
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 03:50:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 03:50:59
Data point term sent to Coder	System	23 Feb 2021 03:49:39
DataPoint Un-verified.	Jessica Fisher (b) (4)	23 Feb 2021 03:49:08
Coding entries removed.	Jessica Fisher (b) (4)	23 Feb 2021 03:49:08
Signature has been broken.	Jessica Fisher (b) (4)	23 Feb 2021 03:49:08
User entered 'partial hysterectomy' reason for change: Data Entry Error	Jessica Fisher (b) (4)	23 Feb 2021 03:49:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:25:43
Data point term sent to Coder	System	16 Sep 2020 19:24:34
User entered 'TOTAL HYSTERECTOMY'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2013'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered 'un UNK 2013'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:23:51
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2013'	System	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2013'	System	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2013'	System	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2013'	System	16 Sep 2020 19:24:32

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 04:18:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 04:18:56
Data point term sent to Coder	System	09 Dec 2020 04:17:46
User entered 'obstructive sleep apnea'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'un UNK 2018'	Jessica Fisher (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Jan 2018'	System	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2018'	System	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	09 Dec 2020 04:17:43

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 04:19:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 04:19:47
Data point term sent to Coder	System	09 Dec 2020 04:18:54
User entered 'recurrent tonsillitis'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'un Feb 2020'	Jessica Fisher (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Jessica Fisher (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:38:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Jessica Fisher (b) (4) (b) (4)	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'Feb 2020'	System	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '2020'	System	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered empty.	System	09 Dec 2020 04:18:04

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered '15:21'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '15 Sep 2020 15:21'	System	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered '170.2' cm	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14
DataPoint set to visible.	System	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered '90.3' kg	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14
DataPoint set to visible.	System	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered '31.17229'	System	16 Sep 2020 19:19:14
DataPoint set to visible.	System	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'kg/m2'	System	16 Sep 2020 19:19:14
DataPoint set to visible.	System	16 Sep 2020 00:37:45

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'bpm'	System	16 Sep 2020 19:19:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'breaths/min'	System	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'mmHg'	System	16 Sep 2020 19:19:14

US3162238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:15
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User entered 'mmHg'	System	16 Sep 2020 19:19:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:50
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:27

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:31:50
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:27

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered 'Surgically sterile (SURGICALLY STERILE)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered 'un UNK 2013'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:17

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:37
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:19:46

US3162238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:48
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:42

US3162238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:48
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:42

US3162238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:48
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:42

US3162238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'VISIT1'	System	16 Sep 2020 19:24:42

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 23:24:17

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered '146041'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 23:24:17

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 23:24:17

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:51

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:51

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:51

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:51

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:33:56
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:24:51

US3162238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:17

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:39:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:27:27
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Completed' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	01 Dec 2020 05:28:16
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	01 Dec 2020 05:28:10
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 20:50:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:18:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:18:32

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '15:21'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '15 Sep 2020 15:21'	System	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '37' C reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:20
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 19:26:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 19:26:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:25
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 19:26:20
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '96' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:20
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'bpm'	System	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '13' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:20
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'breaths/min'	System	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '126' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:20
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '87' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:20
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered missing code ND - Not Done.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '17:39'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '15 Sep 2020 17:39'	System	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '36.6' C	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '84'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'bpm'	System	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '13'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'breaths/min'	System	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '122'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:28
User entered '76'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	16 Sep 2020 19:25:54

US3162238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:40
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:40

US3162238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:35:40
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:26:40

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered '15 Sep 2020'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered '16:58'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '15 Sep 2020 16:58'	System	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered 'Left Arm (LEFT ARM)'	Jourdan Manfred (b) (4) (b) (4)	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:22:30
User entered 'ONCE'	System	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 00:38:14

US3162238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:28
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:11

US3162238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:28
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:11

US3162238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:28
User entered '16:18'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:11

US3162238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '15 Sep 2020 16:18'	System	16 Sep 2020 19:27:11

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:37
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:37
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:37
User entered '16:21'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '15 Sep 2020 16:21'	System	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:37
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:37
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered empty.	System	16 Sep 2020 19:27:19

US3162238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:36:43
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:23

US3162238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	16 Sep 2020 19:27:23

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f9b903b2-436c-4510-a015-b7486cd6c6c9'	System	16 Sep 2020 00:44:20
User entered 'Yes (Y)'	System	16 Sep 2020 00:44:20

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:44:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f9b903b2-436c-4510-a015-b7486cd6c6c9'	System	16 Sep 2020 00:44:20
User entered '97.8'	System	16 Sep 2020 00:44:20

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:44:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f9b903b2-436c-4510-a015-b7486cd6c6c9'	System	16 Sep 2020 00:44:20
User entered 'No (N)'	System	16 Sep 2020 00:44:20

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:44:19', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f9b903b2-436c-4510-a015-b7486cd6c6c9'	System	16 Sep 2020 00:44:20
User entered '15 Sep 2020 17:44'	System	16 Sep 2020 00:44:20

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 17:18'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 19:48'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T10:11:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e6b2edb4-d068-4509-bba6-8a2dde1e1a57'	System	16 Sep 2020 17:12:04
User entered 'Yes (Y)'	System	16 Sep 2020 17:12:04

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T10:11:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e6b2edb4-d068-4509-bba6-8a2dde1e1a57'	System	16 Sep 2020 17:12:04
User entered '97.1'	System	16 Sep 2020 17:12:04

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T10:11:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e6b2edb4-d068-4509-bba6-8a2dde1e1a57'	System	16 Sep 2020 17:12:04
User entered 'No (N)'	System	16 Sep 2020 17:12:04

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T10:12:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e6b2edb4-d068-4509-bba6-8a2dde1e1a57'	System	16 Sep 2020 17:12:04
User entered '16 Sep 2020 10:12'	System	16 Sep 2020 17:12:04

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 2'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:00:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c344ae57-ef2b-4b57-a203-778853f9d018'	System	16 Sep 2020 19:01:09
User entered 'Yes (Y)'	System	16 Sep 2020 19:01:09

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:00:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c344ae57-ef2b-4b57-a203-778853f9d018'	System	16 Sep 2020 19:01:09
User entered '97.1'	System	16 Sep 2020 19:01:09

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:00:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c344ae57-ef2b-4b57-a203-778853f9d018'	System	16 Sep 2020 19:01:09
User entered 'No (N)'	System	16 Sep 2020 19:01:09

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c344ae57-ef2b-4b57-a203-778853f9d018'	System	16 Sep 2020 19:01:09
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 19:01:09

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 3'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:00:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '24dc5ee4-442b-4a97-b8c7-4290aff37744'	System	17 Sep 2020 19:01:34
User entered 'Yes (Y)'	System	17 Sep 2020 19:01:34

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:00:43', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '24dc5ee4-442b-4a97-b8c7-4290aff37744'	System	17 Sep 2020 19:01:34
User entered '97.7'	System	17 Sep 2020 19:01:34

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:00:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '24dc5ee4-442b-4a97-b8c7-4290aff37744'	System	17 Sep 2020 19:01:34
User entered 'No (N)'	System	17 Sep 2020 19:01:34

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:00:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '24dc5ee4-442b-4a97-b8c7-4290aff37744'	System	17 Sep 2020 19:01:34
User entered '17 Sep 2020 12:00'	System	17 Sep 2020 19:01:34

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 4'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:18', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '040982ee-0289-419e-8a97-c90d759673e2'	System	18 Sep 2020 19:47:31
User entered 'Yes (Y)'	System	18 Sep 2020 19:47:31

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:22', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '040982ee-0289-419e-8a97-c90d759673e2'	System	18 Sep 2020 19:47:31
User entered '97.6'	System	18 Sep 2020 19:47:31

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:24', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '040982ee-0289-419e-8a97-c90d759673e2'	System	18 Sep 2020 19:47:31
User entered 'No (N)'	System	18 Sep 2020 19:47:31

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:28', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '040982ee-0289-419e-8a97-c90d759673e2'	System	18 Sep 2020 19:47:31
User entered '18 Sep 2020 12:47'	System	18 Sep 2020 19:47:31

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 5'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:01:45', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b6316eb3-07f3-4a0c-9424-e085104fd43c'	System	19 Sep 2020 19:02:08
User entered 'Yes (Y)'	System	19 Sep 2020 19:02:08

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:01:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b6316eb3-07f3-4a0c-9424-e085104fd43c'	System	19 Sep 2020 19:02:08
User entered '98.1'	System	19 Sep 2020 19:02:08

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:01:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b6316eb3-07f3-4a0c-9424-e085104fd43c'	System	19 Sep 2020 19:02:08
User entered 'No (N)'	System	19 Sep 2020 19:02:08

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b6316eb3-07f3-4a0c-9424-e085104fd43c'	System	19 Sep 2020 19:02:08
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:08

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 6'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:40:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6fe62e19-1e11-4617-99bd-2c49999c569e'	System	20 Sep 2020 20:40:57
User entered 'Yes (Y)'	System	20 Sep 2020 20:40:57

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:40:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6fe62e19-1e11-4617-99bd-2c49999c569e'	System	20 Sep 2020 20:40:57
User entered '98.1'	System	20 Sep 2020 20:40:57

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:40:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6fe62e19-1e11-4617-99bd-2c49999c569e'	System	20 Sep 2020 20:40:57
User entered 'No (N)'	System	20 Sep 2020 20:40:57

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:40:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6fe62e19-1e11-4617-99bd-2c49999c569e'	System	20 Sep 2020 20:40:57
User entered '20 Sep 2020 13:40'	System	20 Sep 2020 20:40:57

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 7'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0a488726-a2c9-4581-b4ba-202790625502'	System	21 Sep 2020 19:31:25
User entered 'Yes (Y)'	System	21 Sep 2020 19:31:25

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:16', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0a488726-a2c9-4581-b4ba-202790625502'	System	21 Sep 2020 19:31:25
User entered '98.3'	System	21 Sep 2020 19:31:25

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:18', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0a488726-a2c9-4581-b4ba-202790625502'	System	21 Sep 2020 19:31:25
User entered 'No (N)'	System	21 Sep 2020 19:31:25

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:26', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0a488726-a2c9-4581-b4ba-202790625502'	System	21 Sep 2020 19:31:25
User entered '21 Sep 2020 12:31'	System	21 Sep 2020 19:31:25

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:21', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9a37a041-c853-4501-81fb-b0ae5195d3de'	System	16 Sep 2020 00:39:55
User entered 'None (1)'	System	16 Sep 2020 00:39:55

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:25', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9a37a041-c853-4501-81fb-b0ae5195d3de'	System	16 Sep 2020 00:39:55
User entered 'No (N)'	System	16 Sep 2020 00:39:55

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:29', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9a37a041-c853-4501-81fb-b0ae5195d3de'	System	16 Sep 2020 00:39:55
User entered 'No (N)'	System	16 Sep 2020 00:39:55

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9a37a041-c853-4501-81fb-b0ae5195d3de'	System	16 Sep 2020 00:39:55
User entered 'None (1)'	System	16 Sep 2020 00:39:55

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:40', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9a37a041-c853-4501-81fb-b0ae5195d3de' User entered '15 Sep 2020 17:39'	System	16 Sep 2020 00:39:55
	System	16 Sep 2020 00:39:55

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 17:18'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 19:48'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 2'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '71ed4eaf-a51a-4d0a-aca2-f612da024309'	System	16 Sep 2020 19:01:26
User entered 'None (1)'	System	16 Sep 2020 19:01:26

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '71ed4eaf-a51a-4d0a-aca2-f612da024309'	System	16 Sep 2020 19:01:26
User entered 'No (N)'	System	16 Sep 2020 19:01:26

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:12', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '71ed4eaf-a51a-4d0a-aca2-f612da024309'	System	16 Sep 2020 19:01:26
User entered 'No (N)'	System	16 Sep 2020 19:01:26

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:17', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '71ed4eaf-a51a-4d0a-aca2-f612da024309'	System	16 Sep 2020 19:01:26
User entered 'None (1)'	System	16 Sep 2020 19:01:26

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:22', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '71ed4eaf-a51a-4d0a-aca2-f612da024309'	System	16 Sep 2020 19:01:26
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 19:01:26

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 3'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:00:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '10f2366d-2468-4f7d-928c-02ec9dff1ee3'	System	17 Sep 2020 19:02:45
User entered 'None (1)'	System	17 Sep 2020 19:02:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:01:28', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '10f2366d-2468-4f7d-928c-02ec9dff1ee3'	System	17 Sep 2020 19:02:45
User entered 'No (N)'	System	17 Sep 2020 19:02:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:01:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '10f2366d-2468-4f7d-928c-02ec9dff1ee3'	System	17 Sep 2020 19:02:45
User entered 'No (N)'	System	17 Sep 2020 19:02:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:01:43', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '10f2366d-2468-4f7d-928c-02ec9dff1ee3'	System	17 Sep 2020 19:02:45
User entered 'None (1)'	System	17 Sep 2020 19:02:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '10f2366d-2468-4f7d-928c-02ec9dff1ee3'	System	17 Sep 2020 19:02:45
User entered '17 Sep 2020 12:02'	System	17 Sep 2020 19:02:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 4'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:31', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e5c4f51d-9ee9-4b3c-a78e-27374f82061a'	System	18 Sep 2020 19:47:45
User entered 'None (1)'	System	18 Sep 2020 19:47:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e5c4f51d-9ee9-4b3c-a78e-27374f82061a'	System	18 Sep 2020 19:47:45
User entered 'No (N)'	System	18 Sep 2020 19:47:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e5c4f51d-9ee9-4b3c-a78e-27374f82061a'	System	18 Sep 2020 19:47:45
User entered 'No (N)'	System	18 Sep 2020 19:47:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e5c4f51d-9ee9-4b3c-a78e-27374f82061a'	System	18 Sep 2020 19:47:45
User entered 'None (1)'	System	18 Sep 2020 19:47:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e5c4f51d-9ee9-4b3c-a78e-27374f82061a'	System	18 Sep 2020 19:47:45
User entered '18 Sep 2020 12:47'	System	18 Sep 2020 19:47:45

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 5'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:16', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bcfc19e-9903-4799-905d-5b08193271ff'	System	19 Sep 2020 19:02:30
User entered 'None (1)'	System	19 Sep 2020 19:02:30

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:18', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bcfc19e-9903-4799-905d-5b08193271ff'	System	19 Sep 2020 19:02:30
User entered 'No (N)'	System	19 Sep 2020 19:02:30

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:21', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bcfc19e-9903-4799-905d-5b08193271ff'	System	19 Sep 2020 19:02:30
User entered 'No (N)'	System	19 Sep 2020 19:02:30

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:24', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bcfc19e-9903-4799-905d-5b08193271ff'	System	19 Sep 2020 19:02:30
User entered 'None (1)'	System	19 Sep 2020 19:02:30

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:28', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bcfc19e-9903-4799-905d-5b08193271ff'	System	19 Sep 2020 19:02:30
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:30

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 6'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'caf479aa-799b-4211-9b36-ca34ba5b499b'	System	20 Sep 2020 20:41:14
User entered 'None (1)'	System	20 Sep 2020 20:41:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'caf479aa-799b-4211-9b36-ca34ba5b499b'	System	20 Sep 2020 20:41:14
User entered 'No (N)'	System	20 Sep 2020 20:41:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:09', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'caf479aa-799b-4211-9b36-ca34ba5b499b'	System	20 Sep 2020 20:41:14
User entered 'No (N)'	System	20 Sep 2020 20:41:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:12', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'caf479aa-799b-4211-9b36-ca34ba5b499b'	System	20 Sep 2020 20:41:14
User entered 'None (1)'	System	20 Sep 2020 20:41:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:15', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'caf479aa-799b-4211-9b36-ca34ba5b499b'	System	20 Sep 2020 20:41:14
User entered '20 Sep 2020 13:41'	System	20 Sep 2020 20:41:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 7'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:30', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '379a95e5-9f85-44e6-88f2-e2d3d33dca0d'	System	21 Sep 2020 19:31:38
User entered 'None (1)'	System	21 Sep 2020 19:31:38

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '379a95e5-9f85-44e6-88f2-e2d3d33dca0d'	System	21 Sep 2020 19:31:38
User entered 'No (N)'	System	21 Sep 2020 19:31:38

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '379a95e5-9f85-44e6-88f2-e2d3d33dca0d'	System	21 Sep 2020 19:31:38
User entered 'No (N)'	System	21 Sep 2020 19:31:38

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:36', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '379a95e5-9f85-44e6-88f2-e2d3d33dca0d'	System	21 Sep 2020 19:31:38
User entered 'None (1)'	System	21 Sep 2020 19:31:38

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '379a95e5-9f85-44e6-88f2-e2d3d33dca0d'	System	21 Sep 2020 19:31:38
User entered '21 Sep 2020 12:31'	System	21 Sep 2020 19:31:38

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:39:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:08', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'None (0)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:14', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered 'No (N)'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-15T17:40:22', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c49f19ec-e048-4dfe-a65c-a6616d206c34'	System	16 Sep 2020 00:40:34
User entered '15 Sep 2020 17:40'	System	16 Sep 2020 00:40:34

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 17:18'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 19:48'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Sep 2020 20:43'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 2'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:30', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:36', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:38', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:45', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'None (0)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered 'No (N)'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-16T12:01:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ef4d0d4-6046-4abb-9a7c-2bd952b50d9b'	System	16 Sep 2020 19:02:05
User entered '16 Sep 2020 12:01'	System	16 Sep 2020 19:02:05

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 3'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:16', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:20', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:22', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:24', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:27', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:29', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'None (0)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:33', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered 'No (N)'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-17T12:02:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c95092fe-fbd3-4b71-bf66-fcac1aa91770'	System	17 Sep 2020 19:02:55
User entered '17 Sep 2020 12:02'	System	17 Sep 2020 19:02:55

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 4'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'None (0)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'None (0)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'None (0)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1' User entered 'None (0)'	System	18 Sep 2020 19:48:04
	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'None (0)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:47:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'None (0)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:48:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered 'No (N)'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-18T12:48:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '0b353466-1592-447d-8bc5-7201d1ac83f1'	System	18 Sep 2020 19:48:04
User entered '18 Sep 2020 12:48'	System	18 Sep 2020 19:48:04

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 5'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:36', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'None (0)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:02:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered 'No (N)'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-19T12:03:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '445f0287-46cd-41a2-bb38-5586e0476bae'	System	19 Sep 2020 19:03:09
User entered '19 Sep 2020 12:03'	System	19 Sep 2020 19:03:09

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 6'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:23', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:29', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:36', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:38', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'None (0)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:40', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered 'No (N)'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-20T13:41:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2809871d-9af2-41fa-b851-8e2c2b6065f5'	System	20 Sep 2020 20:41:44
User entered '20 Sep 2020 13:41'	System	20 Sep 2020 20:41:44

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 7'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:43', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'None (0)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:31:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered 'No (N)'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-09-21T12:32:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7472610c-de70-4715-94c5-912500744d4d'	System	21 Sep 2020 19:32:01
User entered '21 Sep 2020 12:32'	System	21 Sep 2020 19:32:01

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 00:38:14

US3162238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:37:43
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	23 Sep 2020 02:52:38

US3162238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:37:43
User entered '22 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	23 Sep 2020 02:52:38

US3162238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:37:43
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	23 Sep 2020 02:52:38

US3162238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:37:43
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	23 Sep 2020 02:52:38

US3162238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:37:48
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	23 Sep 2020 02:52:43

US3162238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	23 Sep 2020 02:52:43

US3162238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:14
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:04:21

US3162238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:14
User entered '29 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:04:21

US3162238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:14
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:04:21

US3162238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:14
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:04:21

US3162238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:04:24

US3162238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	30 Sep 2020 04:04:24

US3162238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:29
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:15:23

US3162238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:29
User entered '6 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:15:23

US3162238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:29
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:15:23

US3162238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:29
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:15:23

US3162238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:38:33
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 02:15:26

US3162238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	07 Oct 2020 02:15:26

US3162238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:27
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:08

US3162238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:27
User entered '13 Oct 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:07
User entered '20 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:08

US3162238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:27
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:08

US3162238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'VISIT2'	System	21 Oct 2020 16:08:08

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4)	21 Oct 2020 16:08:57
	(b) (4)	

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:10:07
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:08:57
User entered '13 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '13:33'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '13 Oct 2020 13:33'	System	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:09:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Oct 2020 16:09:10
User entered '37.2' C reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:10
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 16:08:57
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '87'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'bpm'	System	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '14' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:10
User entered '13'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'breaths/min'	System	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '137'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '74'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	21 Oct 2020 16:08:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:10:07
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:09:56
User entered '13 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:20:44
User closed query 'Per source, the time of assessment was 15:56, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 19:20:42
Query 'Per source, the time of assessment was 15:56, please verify. Thank you.' answered with 'corrected' (Site from CRA).	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:18:40
DataPoint Un-verified.	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:18:28
User entered '15:56' reason for change: Data Entry Error	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:18:28
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User opened query 'Per source, the time of assessment was 15:56, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 01:51:27
User entered '15:50'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '13 Oct 2020 15:56'	System	02 Feb 2021 20:18:28
User entered '13 Oct 2020 15:50'	System	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '37.3' C	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '70'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'bpm'	System	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '14'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'breaths/min'	System	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '113'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:51:40
User entered '78'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	21 Oct 2020 16:09:56

US3162238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:20:21
User closed query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 19:20:11
Query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' answered with 'corrected' (Site from CRA).	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:08:58
User opened query 'Per Source, a symptom driven PE was not done, please update this question and remove the date below. Thank you.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 01:52:05
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:18

US3162238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:20:21
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Feb 2021 20:13:14
User entered '13 Oct 2020' reason for change: Data Entry Error	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:13:14
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Feb 2021 20:08:48
User entered empty; reason for change Data Entry Error	Marcia Bernard (b) (4) (b) (4)	02 Feb 2021 20:08:48
User entered '13 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:18

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:10:07
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 16:10:07
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:08:08
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered '15:08'	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '13 Oct 2020 15:08'	System	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:49:56
User entered 'ONCE'	System	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 22:55:03

US3162238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:09
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:09
User entered '13 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:50:09
User entered '14:41'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:10:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '13 Oct 2020 14:41'	System	21 Oct 2020 16:10:57

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:27
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:11:17
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 16:11:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 16:11:17
User entered '13 Oct 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 16:11:14
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:11:14
User entered '13 Oct 2020' (non-conformant).	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:27
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:27
User entered '14:50'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '13 Oct 2020 14:50'	System	21 Oct 2020 16:11:17
User entered '13 Oct 2020 14:50' (non-conformant).	System	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:27
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:27
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered empty.	System	21 Oct 2020 16:11:14

US3162238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:52:32
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:29

US3162238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '1'	System	21 Oct 2020 16:07:29

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ac9ba9a6-c9ec-4f46-9840-e37d9cba1efe'	System	13 Oct 2020 22:56:27
User entered 'Yes (Y)'	System	13 Oct 2020 22:56:27

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ac9ba9a6-c9ec-4f46-9840-e37d9cba1efe' User entered '99.1'	System	13 Oct 2020 22:56:27
	System	13 Oct 2020 22:56:27

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:17', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ac9ba9a6-c9ec-4f46-9840-e37d9cba1efe'	System	13 Oct 2020 22:56:27
User entered 'No (N)'	System	13 Oct 2020 22:56:27

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:22', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ac9ba9a6-c9ec-4f46-9840-e37d9cba1efe'	System	13 Oct 2020 22:56:27
User entered '13 Oct 2020 15:56'	System	13 Oct 2020 22:56:27

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 15:28'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 17:58'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:29', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6f53fe39-35e5-4142-8dad-4a514152abd0'	System	14 Oct 2020 02:19:48
User entered 'Yes (Y)'	System	14 Oct 2020 02:19:48

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6f53fe39-35e5-4142-8dad-4a514152abd0'	System	14 Oct 2020 02:19:48
User entered '97.7'	System	14 Oct 2020 02:19:48

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6f53fe39-35e5-4142-8dad-4a514152abd0'	System	14 Oct 2020 02:19:48
User entered 'No (N)'	System	14 Oct 2020 02:19:48

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6f53fe39-35e5-4142-8dad-4a514152abd0'	System	14 Oct 2020 02:19:48
User entered '13 Oct 2020 19:19'	System	14 Oct 2020 02:19:48

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 18:53'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 2'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:08:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2c73ef7a-8894-4011-825c-f7ac59df9943'	System	14 Oct 2020 20:09:35
User entered 'Yes (Y)'	System	14 Oct 2020 20:09:35

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2c73ef7a-8894-4011-825c-f7ac59df9943'	System	14 Oct 2020 20:09:35
User entered '98.9'	System	14 Oct 2020 20:09:35

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:14', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2c73ef7a-8894-4011-825c-f7ac59df9943'	System	14 Oct 2020 20:09:35
User entered 'No (N)'	System	14 Oct 2020 20:09:35

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:31', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2c73ef7a-8894-4011-825c-f7ac59df9943'	System	14 Oct 2020 20:09:35
User entered '14 Oct 2020 13:09'	System	14 Oct 2020 20:09:35

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 3'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:38', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c51ee73d-766e-4448-9ed4-24407e123084'	System	15 Oct 2020 20:34:54
User entered 'Yes (Y)'	System	15 Oct 2020 20:34:54

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c51ee73d-766e-4448-9ed4-24407e123084' User entered '96.0'	System	15 Oct 2020 20:34:54
	System	15 Oct 2020 20:34:54

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c51ee73d-766e-4448-9ed4-24407e123084'	System	15 Oct 2020 20:34:54
User entered 'No (N)'	System	15 Oct 2020 20:34:54

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c51ee73d-766e-4448-9ed4-24407e123084'	System	15 Oct 2020 20:34:54
User entered '15 Oct 2020 13:34'	System	15 Oct 2020 20:34:54

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 4'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '16d155c4-21e7-43d9-b9ec-f2b5de3179b2'	System	16 Oct 2020 19:28:52
User entered 'Yes (Y)'	System	16 Oct 2020 19:28:52

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:41', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '16d155c4-21e7-43d9-b9ec-f2b5de3179b2'	System	16 Oct 2020 19:28:52
User entered '97.6'	System	16 Oct 2020 19:28:52

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '16d155c4-21e7-43d9-b9ec-f2b5de3179b2'	System	16 Oct 2020 19:28:52
User entered 'No (N)'	System	16 Oct 2020 19:28:52

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '16d155c4-21e7-43d9-b9ec-f2b5de3179b2'	System	16 Oct 2020 19:28:52
User entered '16 Oct 2020 12:28'	System	16 Oct 2020 19:28:52

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 5'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:26', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c7d20ff9-24be-4fc0-9c22-e70b2883109e'	System	17 Oct 2020 20:22:43
User entered 'Yes (Y)'	System	17 Oct 2020 20:22:43

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c7d20ff9-24be-4fc0-9c22-e70b2883109e'	System	17 Oct 2020 20:22:43
User entered '97.8'	System	17 Oct 2020 20:22:43

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c7d20ff9-24be-4fc0-9c22-e70b2883109e'	System	17 Oct 2020 20:22:43
User entered 'No (N)'	System	17 Oct 2020 20:22:43

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:41', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c7d20ff9-24be-4fc0-9c22-e70b2883109e'	System	17 Oct 2020 20:22:43
User entered '17 Oct 2020 13:22'	System	17 Oct 2020 20:22:43

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 6'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:20', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2e22fa66-8670-4d11-b9fc-a68eaa26b35b'	System	18 Oct 2020 19:10:32
User entered 'Yes (Y)'	System	18 Oct 2020 19:10:32

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:24', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2e22fa66-8670-4d11-b9fc-a68eaa26b35b'	System	18 Oct 2020 19:10:32
User entered '98.0'	System	18 Oct 2020 19:10:32

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:27', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2e22fa66-8670-4d11-b9fc-a68eaa26b35b'	System	18 Oct 2020 19:10:32
User entered 'No (N)'	System	18 Oct 2020 19:10:32

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:31', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2e22fa66-8670-4d11-b9fc-a68eaa26b35b'	System	18 Oct 2020 19:10:32
User entered '18 Oct 2020 12:10'	System	18 Oct 2020 19:10:32

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 7'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:20:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bee88a7-7fab-4db8-994d-c7e2684d2761'	System	20 Oct 2020 02:21:06
User entered 'Yes (Y)'	System	20 Oct 2020 02:21:06

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:20:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bee88a7-7fab-4db8-994d-c7e2684d2761'	System	20 Oct 2020 02:21:06
User entered '98.1'	System	20 Oct 2020 02:21:06

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bee88a7-7fab-4db8-994d-c7e2684d2761'	System	20 Oct 2020 02:21:06
User entered 'No (N)'	System	20 Oct 2020 02:21:06

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:04', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3bee88a7-7fab-4db8-994d-c7e2684d2761'	System	20 Oct 2020 02:21:06
User entered '19 Oct 2020 19:21'	System	20 Oct 2020 02:21:06

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '5218316f-32c6-43e3-8161-38e393aadd7f'	System	13 Oct 2020 22:56:48
User entered 'None (1)'	System	13 Oct 2020 22:56:48

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '5218316f-32c6-43e3-8161-38e393aadd7f'	System	13 Oct 2020 22:56:48
User entered 'No (N)'	System	13 Oct 2020 22:56:48

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '5218316f-32c6-43e3-8161-38e393aadd7f'	System	13 Oct 2020 22:56:48
User entered 'No (N)'	System	13 Oct 2020 22:56:48

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:40', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '5218316f-32c6-43e3-8161-38e393aadd7f'	System	13 Oct 2020 22:56:48
User entered 'None (1)'	System	13 Oct 2020 22:56:48

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '5218316f-32c6-43e3-8161-38e393aadd7f'	System	13 Oct 2020 22:56:48
User entered '13 Oct 2020 15:56'	System	13 Oct 2020 22:56:48

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 15:28'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 17:58'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b5ae8ff4-6293-44da-bd23-1c957f63505f'	System	14 Oct 2020 02:20:05
User entered 'None (1)'	System	14 Oct 2020 02:20:05

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b5ae8ff4-6293-44da-bd23-1c957f63505f'	System	14 Oct 2020 02:20:05
User entered 'No (N)'	System	14 Oct 2020 02:20:05

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b5ae8ff4-6293-44da-bd23-1c957f63505f'	System	14 Oct 2020 02:20:05
User entered 'No (N)'	System	14 Oct 2020 02:20:05

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:19:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b5ae8ff4-6293-44da-bd23-1c957f63505f'	System	14 Oct 2020 02:20:05
User entered 'None (1)'	System	14 Oct 2020 02:20:05

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b5ae8ff4-6293-44da-bd23-1c957f63505f'	System	14 Oct 2020 02:20:05
User entered '13 Oct 2020 19:20'	System	14 Oct 2020 02:20:05

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 18:53'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 2'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:37', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ebbc33cd-2b99-496c-b70b-c29c3964f489'	System	14 Oct 2020 20:09:56
User entered 'None (1)'	System	14 Oct 2020 20:09:56

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:41', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ebbc33cd-2b99-496c-b70b-c29c3964f489'	System	14 Oct 2020 20:09:56
User entered 'No (N)'	System	14 Oct 2020 20:09:56

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:43', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ebbc33cd-2b99-496c-b70b-c29c3964f489'	System	14 Oct 2020 20:09:56
User entered 'No (N)'	System	14 Oct 2020 20:09:56

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ebbc33cd-2b99-496c-b70b-c29c3964f489'	System	14 Oct 2020 20:09:56
User entered 'None (1)'	System	14 Oct 2020 20:09:56

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ebbc33cd-2b99-496c-b70b-c29c3964f489'	System	14 Oct 2020 20:09:56
User entered '14 Oct 2020 13:09'	System	14 Oct 2020 20:09:56

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 3'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b3d8ccb3-d523-49d1-9943-51ca36ceb241'	System	15 Oct 2020 20:35:08
User entered 'None (1)'	System	15 Oct 2020 20:35:08

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b3d8ccb3-d523-49d1-9943-51ca36ceb241'	System	15 Oct 2020 20:35:08
User entered 'No (N)'	System	15 Oct 2020 20:35:08

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:34:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b3d8ccb3-d523-49d1-9943-51ca36ceb241'	System	15 Oct 2020 20:35:08
User entered 'No (N)'	System	15 Oct 2020 20:35:08

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b3d8ccb3-d523-49d1-9943-51ca36ceb241'	System	15 Oct 2020 20:35:08
User entered 'None (1)'	System	15 Oct 2020 20:35:08

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b3d8ccb3-d523-49d1-9943-51ca36ceb241'	System	15 Oct 2020 20:35:08
User entered '15 Oct 2020 13:35'	System	15 Oct 2020 20:35:08

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 4'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '546414db-4a9f-4247-b86f-1781345d4c55'	System	16 Oct 2020 19:29:01
User entered 'None (1)'	System	16 Oct 2020 19:29:01

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '546414db-4a9f-4247-b86f-1781345d4c55'	System	16 Oct 2020 19:29:01
User entered 'No (N)'	System	16 Oct 2020 19:29:01

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '546414db-4a9f-4247-b86f-1781345d4c55'	System	16 Oct 2020 19:29:01
User entered 'No (N)'	System	16 Oct 2020 19:29:01

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:28:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '546414db-4a9f-4247-b86f-1781345d4c55'	System	16 Oct 2020 19:29:01
User entered 'None (1)'	System	16 Oct 2020 19:29:01

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '546414db-4a9f-4247-b86f-1781345d4c55'	System	16 Oct 2020 19:29:01
User entered '16 Oct 2020 12:29'	System	16 Oct 2020 19:29:01

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 5'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cc493771-34fc-453d-8cc5-873a3b8b602f'	System	17 Oct 2020 20:22:55
User entered 'None (1)'	System	17 Oct 2020 20:22:55

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cc493771-34fc-453d-8cc5-873a3b8b602f'	System	17 Oct 2020 20:22:55
User entered 'No (N)'	System	17 Oct 2020 20:22:55

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cc493771-34fc-453d-8cc5-873a3b8b602f'	System	17 Oct 2020 20:22:55
User entered 'No (N)'	System	17 Oct 2020 20:22:55

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cc493771-34fc-453d-8cc5-873a3b8b602f'	System	17 Oct 2020 20:22:55
User entered 'None (1)'	System	17 Oct 2020 20:22:55

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cc493771-34fc-453d-8cc5-873a3b8b602f'	System	17 Oct 2020 20:22:55
User entered '17 Oct 2020 13:22'	System	17 Oct 2020 20:22:55

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 6'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a5443cb-bce1-4b98-8172-b20604be5ffb'	System	18 Oct 2020 19:10:45
User entered 'None (1)'	System	18 Oct 2020 19:10:45

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:38', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a5443cb-bce1-4b98-8172-b20604be5ffb'	System	18 Oct 2020 19:10:45
User entered 'No (N)'	System	18 Oct 2020 19:10:45

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:40', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a5443cb-bce1-4b98-8172-b20604be5ffb'	System	18 Oct 2020 19:10:45
User entered 'No (N)'	System	18 Oct 2020 19:10:45

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a5443cb-bce1-4b98-8172-b20604be5ffb'	System	18 Oct 2020 19:10:45
User entered 'None (1)'	System	18 Oct 2020 19:10:45

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:45', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a5443cb-bce1-4b98-8172-b20604be5ffb'	System	18 Oct 2020 19:10:45
User entered '18 Oct 2020 12:10'	System	18 Oct 2020 19:10:45

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 7'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:09', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2fa30e7a-4647-4289-995d-f6fcefcc8966'	System	20 Oct 2020 02:21:22
User entered 'None (1)'	System	20 Oct 2020 02:21:22

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2fa30e7a-4647-4289-995d-f6fcefcc8966'	System	20 Oct 2020 02:21:22
User entered 'No (N)'	System	20 Oct 2020 02:21:22

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2fa30e7a-4647-4289-995d-f6fcefcc8966'	System	20 Oct 2020 02:21:22
User entered 'No (N)'	System	20 Oct 2020 02:21:22

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:15', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2fa30e7a-4647-4289-995d-f6fcefcc8966'	System	20 Oct 2020 02:21:22
User entered 'None (1)'	System	20 Oct 2020 02:21:22

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:19', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2fa30e7a-4647-4289-995d-f6fcefcc8966'	System	20 Oct 2020 02:21:22
User entered '19 Oct 2020 19:21'	System	20 Oct 2020 02:21:22

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:56', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:56:59', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:57:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'None (0)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:57:04', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered 'No (N)'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T15:57:09', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'cdd6e3a6-726f-4e3f-aeee-0bd10efd67db'	System	13 Oct 2020 22:57:12
User entered '13 Oct 2020 15:57'	System	13 Oct 2020 22:57:12

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 15:28'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 17:58'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:05', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:08', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'None (0)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:15', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered 'No (N)'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-13T19:20:17', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f6c04227-39a4-405f-9c07-21b3c3c2a103'	System	14 Oct 2020 02:20:21
User entered '13 Oct 2020 19:20'	System	14 Oct 2020 02:20:21

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '13 Oct 2020 18:53'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 2'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:09:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:04', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:08', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'None (0)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered 'No (N)'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-14T13:10:14', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ea62f3e7-7ab7-4237-bbb8-05c285af18b9'	System	14 Oct 2020 20:10:18
User entered '14 Oct 2020 13:10'	System	14 Oct 2020 20:10:18

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 3'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:08', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:12', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:15', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:17', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'None (0)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:19', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered 'No (N)'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-15T13:35:23', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'af04e37f-4b5d-400e-b1d4-03ef3d0703d5'	System	15 Oct 2020 20:35:26
User entered '15 Oct 2020 13:35'	System	15 Oct 2020 20:35:26

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 4'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:04', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'None (0)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'None (0)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'None (0)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'None (0)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:18', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:21', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'None (0)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:26', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered 'Yes (Y)'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-16T12:29:28', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '62e57afd-506e-4715-8d7c-937b195ad5f1'	System	16 Oct 2020 19:29:30
User entered '16 Oct 2020 12:29'	System	16 Oct 2020 19:29:30

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 5'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:22:59', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:04', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:07', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'None (0)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:10', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered 'No (N)'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-17T13:23:13', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '45dc7204-ead7-4838-97eb-7df813b87aaf'	System	17 Oct 2020 20:23:15
User entered '17 Oct 2020 13:23'	System	17 Oct 2020 20:23:15

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 6'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:50', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:10:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:11:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'None (0)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:11:03', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered 'No (N)'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-18T12:11:06', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'bcfff947-1b40-4ee9-959d-97060f8c5787'	System	18 Oct 2020 19:11:07
User entered '18 Oct 2020 12:11'	System	18 Oct 2020 19:11:07

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	13 Oct 2020 22:55:03
User entered 'Day 7'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:23', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:25', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:27', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:29', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:31', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:33', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'None (0)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered 'No (N)'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-10-19T19:21:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '2729818d-5449-4c23-86a7-0332d87bc93c'	System	20 Oct 2020 02:21:43
User entered '19 Oct 2020 19:21'	System	20 Oct 2020 02:21:43

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 22:55:03

US3162238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 22:55:03

US3162238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:00
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:40

US3162238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:00
User entered '20 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:40

US3162238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:00
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:40

US3162238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:00
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:40

US3162238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:06
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:07:44

US3162238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	21 Oct 2020 16:07:44

US3162238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:31
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Oct 2020 16:45:14

US3162238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:31
User entered '27 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Oct 2020 16:45:14

US3162238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:31
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Oct 2020 16:45:14

US3162238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:31
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Oct 2020 16:45:14

US3162238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:35
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Oct 2020 16:45:18

US3162238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	28 Oct 2020 16:45:18

US3162238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:45
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	04 Nov 2020 03:17:15

US3162238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:45
User entered '3 Nov 2020'	Jessica Fisher (b) (4)	04 Nov 2020 03:17:15

US3162238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:45
User entered 'Contact Made (CONTACT MADE)'	Jessica Fisher (b) (4)	04 Nov 2020 03:17:15

US3162238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:45
User entered empty.	Jessica Fisher (b) (4)	04 Nov 2020 03:17:15

US3162238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:54:50
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	04 Nov 2020 03:17:20

US3162238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '1'	System	04 Nov 2020 03:17:20

US3162238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:55:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:05:33

US3162238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:55:12
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:05:33

US3162238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[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 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:55:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 18:05:33

US3162238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'VISIT3'	System	12 Nov 2020 18:05:33

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '09:15'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '10 Nov 2020 09:15'	System	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '98.8' F	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '86'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'bpm'	System	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '14'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'breaths/min'	System	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '129'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:20
User entered '79'	(b) (4), (b) (6)	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'mmHg'	System	12 Nov 2020 18:06:54

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18

US3162238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18

US3162238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 18:07:01

US3162238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:28
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:01

US3162238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:07:25

US3162238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:38
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:07:25

US3162238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:38
User entered '10:09'	(b) (4), (b) (6)	12 Nov 2020 18:07:25

US3162238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered '10 Nov 2020 10:09'	System	12 Nov 2020 18:07:25

US3162238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 01:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:07:35

US3162238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	12 Nov 2020 18:07:35

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered 'Day 64'	System	16 Sep 2020 00:38:14

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-11-16T11:12:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ff0478d-f149-42be-aeb9-984daf8056bc'	System	16 Nov 2020 19:13:04
User entered 'No (N)'	System	16 Nov 2020 19:13:04

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-11-16T11:12:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ff0478d-f149-42be-aeb9-984daf8056bc'	System	16 Nov 2020 19:13:04
User entered 'No (N)'	System	16 Nov 2020 19:13:04

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-11-16T11:13:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7ff0478d-f149-42be-aeb9-984daf8056bc'	System	16 Nov 2020 19:13:04
User entered '16 Nov 2020 11:13:02'	System	16 Nov 2020 19:13:04

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered '15 Nov 2020 00:01'	System	16 Sep 2020 00:38:14

US3162238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:05:09
Data entry locked.	System	16 Sep 2020 00:38:14
User entered '19 Nov 2020 23:59'	System	16 Sep 2020 00:38:14

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-11-22T00:02:05', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '218a4a09-6c9f-4d1b-ba96-d5648b270c44'	System	22 Nov 2020 08:02:22
User entered 'No (N)'	System	22 Nov 2020 08:02:22

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-11-22T00:02:11', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '218a4a09-6c9f-4d1b-ba96-d5648b270c44'	System	22 Nov 2020 08:02:22
User entered 'No (N)'	System	22 Nov 2020 08:02:22

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-11-22T00:02:17', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '218a4a09-6c9f-4d1b-ba96-d5648b270c44'	System	22 Nov 2020 08:02:22
User entered '22 Nov 2020 00:02:17'	System	22 Nov 2020 08:02:22

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-11-27T11:25:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '06d28f8c-8b66-4015-b7eb-75154704faf7'	System	27 Nov 2020 19:25:51
User entered 'No (N)'	System	27 Nov 2020 19:25:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-11-27T11:25:45', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '06d28f8c-8b66-4015-b7eb-75154704faf7'	System	27 Nov 2020 19:25:51
User entered 'No (N)'	System	27 Nov 2020 19:25:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-11-27T11:25:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '06d28f8c-8b66-4015-b7eb-75154704faf7'	System	27 Nov 2020 19:25:51
User entered '27 Nov 2020 11:25:48'	System	27 Nov 2020 19:25:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-12-03T21:23:44', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3cc256b8-cc38-4f62-9c4f-a1576b1d4771'	System	04 Dec 2020 05:23:53
User entered 'No (N)'	System	04 Dec 2020 05:23:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-12-03T21:23:47', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3cc256b8-cc38-4f62-9c4f-a1576b1d4771'	System	04 Dec 2020 05:23:53
User entered 'No (N)'	System	04 Dec 2020 05:23:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-12-03T21:23:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3cc256b8-cc38-4f62-9c4f-a1576b1d4771'	System	04 Dec 2020 05:23:53
User entered '03 Dec 2020 21:23:51'	System	04 Dec 2020 05:23:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-12-10T11:47:46', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '288ead54-bdf2-4aa3-adae-9377ea4190fe'	System	10 Dec 2020 19:47:57
User entered 'No (N)'	System	10 Dec 2020 19:47:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-12-10T11:47:48', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '288ead54-bdf2-4aa3-adae-9377ea4190fe'	System	10 Dec 2020 19:47:57
User entered 'No (N)'	System	10 Dec 2020 19:47:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-12-10T11:47:52', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '288ead54-bdf2-4aa3-adae-9377ea4190fe' User entered '10 Dec 2020 11:47:52'	System	10 Dec 2020 19:47:57
	System	10 Dec 2020 19:47:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-12-17T04:02:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e8022dd8-af06-4a3a-988b-69a4c291b212'	System	17 Dec 2020 12:02:54
User entered 'No (N)'	System	17 Dec 2020 12:02:54

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-12-17T04:02:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e8022dd8-af06-4a3a-988b-69a4c291b212'	System	17 Dec 2020 12:02:54
User entered 'No (N)'	System	17 Dec 2020 12:02:54

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-12-17T04:02:53', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e8022dd8-af06-4a3a-988b-69a4c291b212'	System	17 Dec 2020 12:02:54
User entered '17 Dec 2020 04:02:53'	System	17 Dec 2020 12:02:54

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-12-24T02:33:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'd86521f0-b495-45eb-8677-c90402acf6b9'	System	24 Dec 2020 10:33:40
User entered 'No (N)'	System	24 Dec 2020 10:33:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-12-24T02:33:35', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'd86521f0-b495-45eb-8677-c90402acf6b9'	System	24 Dec 2020 10:33:40
User entered 'No (N)'	System	24 Dec 2020 10:33:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-12-24T02:33:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'd86521f0-b495-45eb-8677-c90402acf6b9'	System	24 Dec 2020 10:33:40
User entered '24 Dec 2020 02:33:39'	System	24 Dec 2020 10:33:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2020-12-31T07:27:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '47c41e0f-cdca-4200-88d7-c75108df89c7'	System	31 Dec 2020 15:27:38
User entered 'No (N)'	System	31 Dec 2020 15:27:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2020-12-31T07:27:34', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '47c41e0f-cdca-4200-88d7-c75108df89c7'	System	31 Dec 2020 15:27:38
User entered 'No (N)'	System	31 Dec 2020 15:27:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2020-12-31T07:27:38', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '47c41e0f-cdca-4200-88d7-c75108df89c7'	System	31 Dec 2020 15:27:38
User entered '31 Dec 2020 07:27:38'	System	31 Dec 2020 15:27:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-01-07T16:32:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '14cca7cc-0a14-4b8e-8412-c66d3952d8bd'	System	08 Jan 2021 00:33:04
User entered 'No (N)'	System	08 Jan 2021 00:33:04

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-01-07T16:32:59', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '14cca7cc-0a14-4b8e-8412-c66d3952d8bd'	System	08 Jan 2021 00:33:04
User entered 'No (N)'	System	08 Jan 2021 00:33:04

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-01-07T16:33:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '14cca7cc-0a14-4b8e-8412-c66d3952d8bd' User entered '07 Jan 2021 16:33:02'	System	08 Jan 2021 00:33:04

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-01-14T00:34:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '74865792-f2bd-4c80-bb6c-92e6216e7649'	System	14 Jan 2021 08:35:02
User entered 'No (N)'	System	14 Jan 2021 08:35:02

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-01-14T00:34:57', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '74865792-f2bd-4c80-bb6c-92e6216e7649'	System	14 Jan 2021 08:35:02
User entered 'No (N)'	System	14 Jan 2021 08:35:02

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-01-14T00:35:01', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '74865792-f2bd-4c80-bb6c-92e6216e7649' User entered '14 Jan 2021 00:35:01'	System	14 Jan 2021 08:35:02

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-01-21T00:01:55', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '596be185-8c9a-41ae-b66e-cc658edbe4f5'	System	21 Jan 2021 08:02:05
User entered 'No (N)'	System	21 Jan 2021 08:02:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-01-21T00:01:58', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '596be185-8c9a-41ae-b66e-cc658edbe4f5'	System	21 Jan 2021 08:02:05
User entered 'No (N)'	System	21 Jan 2021 08:02:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-01-21T00:02:02', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '596be185-8c9a-41ae-b66e-cc658edbe4f5'	System	21 Jan 2021 08:02:05
User entered '21 Jan 2021 00:02:02'	System	21 Jan 2021 08:02:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-01-28T10:25:49', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b29d1464-0811-4a79-842f-e21cc4d093bf'	System	28 Jan 2021 18:25:57
User entered 'No (N)'	System	28 Jan 2021 18:25:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-01-28T10:25:51', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b29d1464-0811-4a79-842f-e21cc4d093bf'	System	28 Jan 2021 18:25:57
User entered 'No (N)'	System	28 Jan 2021 18:25:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-01-28T10:25:54', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b29d1464-0811-4a79-842f-e21cc4d093bf' User entered '28 Jan 2021 10:25:54'	System	28 Jan 2021 18:25:57

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-02-04T00:01:28', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'a9bf4a75-d416-431f-935a-10ec3287a7b2'	System	04 Feb 2021 08:02:38
User entered 'No (N)'	System	04 Feb 2021 08:02:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-02-04T00:01:32', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'a9bf4a75-d416-431f-935a-10ec3287a7b2'	System	04 Feb 2021 08:02:38
User entered 'No (N)'	System	04 Feb 2021 08:02:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-04T00:01:39', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'a9bf4a75-d416-431f-935a-10ec3287a7b2'	System	04 Feb 2021 08:02:38
User entered '04 Feb 2021 00:01:39'	System	04 Feb 2021 08:02:38

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-02-11T13:22:40', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9be4a956-6ff5-4617-a910-4bd1e080b330'	System	11 Feb 2021 21:22:52
User entered 'No (N)'	System	11 Feb 2021 21:22:52

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-02-11T13:22:42', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9be4a956-6ff5-4617-a910-4bd1e080b330'	System	11 Feb 2021 21:22:52
User entered 'No (N)'	System	11 Feb 2021 21:22:52

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-11T13:22:45', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '9be4a956-6ff5-4617-a910-4bd1e080b330'	System	11 Feb 2021 21:22:52
User entered '11 Feb 2021 13:22:45'	System	11 Feb 2021 21:22:52

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-02-18T02:37:21', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e50a233e-bc3a-4adc-9766-78767800dbdb'	System	18 Feb 2021 10:37:30
User entered 'No (N)'	System	18 Feb 2021 10:37:30

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-02-18T02:37:23', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e50a233e-bc3a-4adc-9766-78767800dbdb'	System	18 Feb 2021 10:37:30
User entered 'No (N)'	System	18 Feb 2021 10:37:30

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-18T02:37:26', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'e50a233e-bc3a-4adc-9766-78767800dbdb' User entered '18 Feb 2021 02:37:26'	System	18 Feb 2021 10:37:30
	System	18 Feb 2021 10:37:30

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-02-25T00:01:41-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f816dd4d-a221-473c-8d32-a6921ff1bc08'	System	25 Feb 2021 08:01:53
User entered 'No (N)'	System	25 Feb 2021 08:01:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-02-25T00:01:44-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f816dd4d-a221-473c-8d32-a6921ff1bc08'	System	25 Feb 2021 08:01:53
User entered 'No (N)'	System	25 Feb 2021 08:01:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-25T00:01:50-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f816dd4d-a221-473c-8d32-a6921ff1bc08'	System	25 Feb 2021 08:01:53
User entered '25 Feb 2021 00:01:50'	System	25 Feb 2021 08:01:53

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-04T00:57:16-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7496c680-cd33-493e-9a76-b3169b09d5d3'	System	04 Mar 2021 08:57:31
User entered 'No (N)'	System	04 Mar 2021 08:57:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-03-04T00:57:20-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7496c680-cd33-493e-9a76-b3169b09d5d3'	System	04 Mar 2021 08:57:31
User entered 'No (N)'	System	04 Mar 2021 08:57:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-03-04T00:57:28-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '7496c680-cd33-493e-9a76-b3169b09d5d3'	System	04 Mar 2021 08:57:31
User entered '04 Mar 2021 00:57:28'	System	04 Mar 2021 08:57:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:01:12-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e' User entered 'Yes (Y)'	System	11 Mar 2021 08:02:43
	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:01:24-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e'	System	11 Mar 2021 08:02:43
User entered 'No (N)'	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:01:30-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e'	System	11 Mar 2021 08:02:43
User entered 'No (N)'	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:01:55-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e' User entered 'Yes (Y)'	System	11 Mar 2021 08:02:43
	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Please 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 (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:02:18-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e'	System	11 Mar 2021 08:02:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-03-11T00:02:31-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '12cb3e0c-4e4a-4a24-9b9f-991f84e7c30e' User entered '11 Mar 2021 00:02:31'	System	11 Mar 2021 08:02:43
	System	11 Mar 2021 08:02:43

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-18T05:32:38-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'fc944877-3b12-4bc2-ba52-2b72058c7e03'	System	18 Mar 2021 12:32:48
User entered 'No (N)'	System	18 Mar 2021 12:32:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-03-18T05:32:42-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'fc944877-3b12-4bc2-ba52-2b72058c7e03'	System	18 Mar 2021 12:32:48
User entered 'No (N)'	System	18 Mar 2021 12:32:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-03-18T05:32:45-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'fc944877-3b12-4bc2-ba52-2b72058c7e03'	System	18 Mar 2021 12:32:48
User entered '18 Mar 2021 05:32:45'	System	18 Mar 2021 12:32:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-26T08:03:15-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c8e4d37a-5d51-47c1-ad62-7069b9d21718'	System	26 Mar 2021 15:03:48
User entered 'Yes (Y)'	System	26 Mar 2021 15:03:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-03-26T08:03:21-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c8e4d37a-5d51-47c1-ad62-7069b9d21718'	System	26 Mar 2021 15:03:48
User entered 'No (N)'	System	26 Mar 2021 15:03:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-26T08:03:27-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c8e4d37a-5d51-47c1-ad62-7069b9d21718'	System	26 Mar 2021 15:03:48
User entered 'No (N)'	System	26 Mar 2021 15:03:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-03-26T08:03:39-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c8e4d37a-5d51-47c1-ad62-7069b9d21718'	System	26 Mar 2021 15:03:48
User entered 'No (N)'	System	26 Mar 2021 15:03:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-03-26T08:03:47-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'c8e4d37a-5d51-47c1-ad62-7069b9d21718' User entered '26 Mar 2021 08:03:47'	System	26 Mar 2021 15:03:48
	System	26 Mar 2021 15:03:48

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-04-01T00:02:07-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '768bcc2a-f29a-4566-8d9c-1598fc4a052a' User entered 'No (N)'	System	01 Apr 2021 07:02:15
	System	01 Apr 2021 07:02:15

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-04-01T00:02:09-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '768bcc2a-f29a-4566-8d9c-1598fc4a052a'	System	01 Apr 2021 07:02:15
User entered 'No (N)'	System	01 Apr 2021 07:02:15

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-04-01T00:02:12-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '768bcc2a-f29a-4566-8d9c-1598fc4a052a'	System	01 Apr 2021 07:02:15
User entered '01 Apr 2021 00:02:12'	System	01 Apr 2021 07:02:15

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-04-08T07:37:31-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f3b5db88-7e38-4f05-bdc3-4c07e74d0209'	System	08 Apr 2021 14:37:40
User entered 'No (N)'	System	08 Apr 2021 14:37:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-04-08T07:37:33-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f3b5db88-7e38-4f05-bdc3-4c07e74d0209'	System	08 Apr 2021 14:37:40
User entered 'No (N)'	System	08 Apr 2021 14:37:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-04-08T07:37:37-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'f3b5db88-7e38-4f05-bdc3-4c07e74d0209' User entered '08 Apr 2021 07:37:37'	System	08 Apr 2021 14:37:40
	System	08 Apr 2021 14:37:40

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-04-15T00:40:44-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3d8cfef0-b520-4c43-8992-8a126f41d6e6' User entered 'No (N)'	System	15 Apr 2021 07:40:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-04-15T00:40:46-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3d8cfef0-b520-4c43-8992-8a126f41d6e6'	System	15 Apr 2021 07:40:51
User entered 'No (N)'	System	15 Apr 2021 07:40:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-04-15T00:40:49-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '3d8cfef0-b520-4c43-8992-8a126f41d6e6'	System	15 Apr 2021 07:40:51
User entered '15 Apr 2021 00:40:49'	System	15 Apr 2021 07:40:51

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-04-22T23:43:24-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a0c7c90-480e-4f50-b9e3-93b317231cd5'	System	23 Apr 2021 06:43:33
User entered 'No (N)'	System	23 Apr 2021 06:43:33

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-04-22T23:43:27-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a0c7c90-480e-4f50-b9e3-93b317231cd5'	System	23 Apr 2021 06:43:33
User entered 'No (N)'	System	23 Apr 2021 06:43:33

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-04-22T23:43:30-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: '6a0c7c90-480e-4f50-b9e3-93b317231cd5'	System	23 Apr 2021 06:43:33
User entered '22 Apr 2021 23:43:30'	System	23 Apr 2021 06:43:33

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[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 (da9b37c3d8d6e0ed)', Time: '2021-04-29T06:29:15-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ef38f638-8650-4db1-b87d-5e16ace317ed'	System	29 Apr 2021 13:29:31
User entered 'No (N)'	System	29 Apr 2021 13:29:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

Have you been exposed to someone with 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 (da9b37c3d8d6e0ed)', Time: '2021-04-29T06:29:18-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ef38f638-8650-4db1-b87d-5e16ace317ed'	System	29 Apr 2021 13:29:31
User entered 'No (N)'	System	29 Apr 2021 13:29:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-04-29T06:29:22-07:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'ef38f638-8650-4db1-b87d-5e16ace317ed'	System	29 Apr 2021 13:29:31
User entered '29 Apr 2021 06:29:22'	System	29 Apr 2021 13:29:31

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:49:05

US3162238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:49:05
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:49:05

US3162238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:17

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 21:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-28T15:15:43-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b65e6e2a-354c-4305-bea8-f03d8ce8c582'	System	28 Feb 2021 23:18:00
User entered 'No (N)'	System	28 Feb 2021 23:18:00

US3162238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (da9b37c3d8d6e0ed)', Time: '2021-02-28T15:15:54-08:00', User OID: 'PatientReportedOutcome (US3162238)', ODM File OID: 'b65e6e2a-354c-4305-bea8-f03d8ce8c582' User entered '28 Feb 2021 15:15:54'	System	28 Feb 2021 23:18:00
	System	28 Feb 2021 23:18:00

US3162238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:55:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	10 Dec 2020 00:15:24

US3162238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:55:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '8 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	10 Dec 2020 00:15:24

US3162238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:55:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	10 Dec 2020 00:15:24

US3162238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:55:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	10 Dec 2020 00:15:24

US3162238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:58:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	10 Dec 2020 00:15:35

US3162238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:36:18
User entered 'I'	System	10 Dec 2020 00:15:35

US3162238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:59:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 19:31:35

US3162238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:59:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '11 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 19:31:35

US3162238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:59:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 19:31:35

US3162238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:59:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 19:31:35

US3162238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:01:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 19:31:41

US3162238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User entered 'I'	System	13 Jan 2021 19:31:41

US3162238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:01:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 18:15:24

US3162238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:01:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '10 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 18:15:24

US3162238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:01:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 18:15:24

US3162238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:01:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 18:15:24

US3162238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:02:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Feb 2021 18:15:30

US3162238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User entered 'I'	System	12 Feb 2021 18:15:30

US3162238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:12:22
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	15 Mar 2021 15:35:36

US3162238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:12:22
User entered '12 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	15 Mar 2021 15:35:36

US3162238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:12:22
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	15 Mar 2021 15:35:36

US3162238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:12:22
User entered empty.	Tiffany Williams (b) (4) (b) (4)	15 Mar 2021 15:35:36

US3162238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:12:49
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	15 Mar 2021 15:35:44

US3162238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:06:08
User entered 'I'	System	15 Mar 2021 15:35:44

US3162238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:27:02

fb

US3162238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered '13 Apr 2021'	(b) (4), (b) (6)	14 Apr 2021 17:27:02

US3162238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Apr 2021 17:27:02

US3162238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 17:27:02

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:27:20

US3162238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 17:27:43

US3162238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:27:43

US3162238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:28:10

US3162238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered '13 Apr 2021'	(b) (4), (b) (6)	14 Apr 2021 17:28:10

US3162238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered '11:58'	(b) (4), (b) (6)	14 Apr 2021 17:28:10

US3162238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 11:58'	System	14 Apr 2021 17:28:10

US3162238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 17:28:36

US3162238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 17:28:36

US3162238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:02:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:22

US3162238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:02:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:22

US3162238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[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 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:02:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:22

US3162238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 20:59:22

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[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 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:55:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:27:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:08:13

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:55:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:27:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:08:13

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 04:47:07
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 04:47:07
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:03:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '1'	System	12 Jan 2021 20:59:37

US3162238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '1'	System	12 Jan 2021 20:59:37

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '67' in	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '199' lb	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '31.23298'	System	13 Jan 2021 20:40:50
DataPoint set to visible.	System	12 Jan 2021 20:59:37

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '67' in	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '199' lb	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '31.23298'	System	13 Jan 2021 20:40:50
DataPoint set to visible.	System	12 Jan 2021 20:59:37

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User closed query 'Per eSource pre-dose vital signs were collected. Please add data. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 16:34:20
Query 'Per eSource pre-dose vital signs were collected. Please add data. ' answered with 'updated to yes, per source. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 22:29:10
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User opened query 'Per eSource pre-dose vital signs were collected. Please add data. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 21:12:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '12 Jan 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User entered '11:35' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 22:28:54
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '11:00' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '12 Jan 2021 11:35'	System	18 Mar 2021 22:28:54
User entered '12 Jan 2021 11:00'	System	09 Mar 2021 06:28:56
User entered empty.	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '99.1' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 22:28:54
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '83' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'bpm'	System	09 Mar 2021 06:28:56
User entered empty.	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '13' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'breaths/min'	System	09 Mar 2021 06:28:56
User entered empty.	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User entered '137' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 22:28:54
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '146' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'mmHg'	System	09 Mar 2021 06:28:56
User entered empty.	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 16:34:25
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 22:28:54
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User entered '89' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	09 Mar 2021 06:28:56
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'mmHg'	System	09 Mar 2021 06:28:56
User entered empty.	System	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '67' in	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '199' lb	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '31.23298'	System	13 Jan 2021 20:40:50
DataPoint set to visible.	System	12 Jan 2021 20:59:37

US3162238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '13:05'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '12 Jan 2021 13:05'	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '98.7' F	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '86'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'bpm'	System	13 Jan 2021 20:40:50

US3162238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '14'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'breaths/min'	System	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '137'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'mmHg'	System	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '82'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:40:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'mmHg'	System	13 Jan 2021 20:40:50

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:41:05

US3162238

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:41:05

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

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 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'mRNA-1273'	System	12 Jan 2021 21:00:08
DataPoint set to visible.	System	12 Jan 2021 20:59:37

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12:29'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '12 Jan 2021 12:29'	System	12 Jan 2021 21:00:08

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	12 Jan 2021 21:00:08

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:13:47
User entered 'ONCE'	System	12 Jan 2021 21:00:08

US3162238

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 21:00:08

US3162238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:42:19

US3162238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:42:19

US3162238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:20
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '11:09'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:42:19

US3162238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '12 Jan 2021 11:09'	System	13 Jan 2021 20:42:19

US3162238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:43:09

US3162238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '12 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:43:09

US3162238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:10:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '11:03'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:43:09

US3162238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '12 Jan 2021 11:03'	System	13 Jan 2021 20:43:09

US3162238

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

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:14:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	13 Jan 2021 20:43:15

US3162238

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

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:20
User entered '1'	System	13 Jan 2021 20:43:15

US3162238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:17:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	19 Jan 2021 23:46:23
	(b) (4)	

US3162238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:17:42
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 08:24:50
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call was accidentally scheduled one day early' (Site from System).	Judith Kirstein (b) (4)	17 Feb 2021 18:15:44
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	17 Feb 2021 01:43:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
User entered '18 Jan 2021'	Tiffany Williams (b) (4)	19 Jan 2021 23:46:23

US3162238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:17:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	19 Jan 2021 23:46:23
	(b) (4)	

US3162238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:17:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4)	19 Jan 2021 23:46:23

US3162238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:17:58
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	19 Jan 2021 23:46:31
	(b) (4)	

US3162238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
User entered 'I'	System	19 Jan 2021 23:46:31

US3162238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:39:45
User entered 'I'	System	19 Jan 2021 23:46:31
DataPoint set to visible.	System	19 Jan 2021 23:46:31

US3162238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:06:53

US3162238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:06:53

US3162238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

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 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:06:53

US3162238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'OLD29'	System	11 Feb 2021 20:06:53

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '09:26'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered '11 Feb 2021 09:26'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '98.0' F	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered empty.	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '88'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'bpm'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '16'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'breaths/min'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '123'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'mmHg'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:18:46
User entered '74'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'mmHg'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '11:18'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered '11 Feb 2021 11:18'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '98.3' F	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered empty.	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '92'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'bpm'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '14'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'breaths/min'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '134'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'mmHg'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:17
User entered '80'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'mmHg'	System	15 Feb 2021 18:58:58

US3162238

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:00
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:26
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:59:14

US3162238

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:00
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:26
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	15 Feb 2021 18:59:14

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
	(b) (4)	
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).	System	11 Feb 2021 20:08:16
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 by data change (Site from System).	System	11 Feb 2021 20:08:16
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	11 Feb 2021 20:07:34
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	11 Feb 2021 20:07:34
	(b) (4)	

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

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 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered empty.	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'mRNA-1273'	System	11 Feb 2021 20:07:34
DataPoint set to visible.	System	19 Jan 2021 23:46:31

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '11 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered '10:43' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:08:16
User entered empty.	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered '11 Feb 2021 10:43'	System	11 Feb 2021 20:08:16
User entered empty.	System	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:19:55
User entered 'ONCE'	System	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:17

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 20:07:34

US3162238

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	11 Feb 2021 20:08:25

US3162238

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:37
User entered 'I'	System	11 Feb 2021 20:08:25

US3162238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:06
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	19 Feb 2021 20:19:07

US3162238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:06
User entered '18 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	19 Feb 2021 20:19:07

US3162238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:06
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	19 Feb 2021 20:19:07

US3162238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:06
User entered empty.	Tiffany Williams (b) (4) (b) (4)	19 Feb 2021 20:19:07

US3162238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:22:06
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	19 Feb 2021 20:19:14

US3162238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:29
User entered 'I'	System	19 Feb 2021 20:19:14

US3162238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:30:02
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:47:18

US3162238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:30:02
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 14:06:33
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'PER SPURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:48:22
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Feb 2021 19:47:18
User entered '22 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:47:18

US3162238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:30:02
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:47:18

US3162238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered 'OLD57'	System	23 Feb 2021 19:47:18

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered empty.	System	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:29:56
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[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	23 Feb 2021 19:49:00

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

US3162238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01

US3162238

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:23:50
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:10

US3162238

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:23:50
User entered empty.	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:10

US3162238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:23:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:36

US3162238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:23:56
User entered '22 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:36

US3162238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

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) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:23:56
User entered '14:43'	Tiffany Williams (b) (4) (b) (4)	23 Feb 2021 19:49:36

US3162238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:55:01
User entered '22 Feb 2021 14:43'	System	23 Feb 2021 19:49:36

US3162238

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:31:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:11
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:12:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:31

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:14:47
Data point term sent to Coder	System	21 Oct 2020 16:13:59
User entered 'Sore throat'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '20 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:45:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 18:07:02
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4)	21 Oct 2020 18:07:02
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 18:06:19
User entered '06:00' reason for change: Data Entry Error	Judith Kirstein (b) (4)	21 Oct 2020 18:06:19
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 16:13:55
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	21 Oct 2020 16:13:55
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Oct 2020 16:13:41
User entered '06:00'	Cynthia Kunakom (b) (4)	21 Oct 2020 16:13:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:07:02
User entered '20 Oct 2020 06:00'	System	21 Oct 2020 18:06:19
User entered empty.	System	21 Oct 2020 16:13:55
User entered '20 Oct 2020 06:00'	System	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 18:06:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '20 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 18:06:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Oct 2020 18:07:02
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 18:07:02
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Oct 2020 18:06:19
User entered '22:00' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 18:06:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:07:02
User entered '20 Oct 2020 22:00'	System	21 Oct 2020 18:06:19
User entered empty.	System	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'None (NONE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 18:06:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:35
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 16:13:41

US3162238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:40
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:04
User entered 'USA-US074-2021-mRNA-1273-P301000019'	System	12 Mar 2021 15:55:20
User entered 'New'	(b) (4), (b) (6)	12 Mar 2021 15:55:20

US3162238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:13:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:13:52
Data point term sent to Coder	System	12 Mar 2021 00:36:18
User entered 'Post-operative hypoxia'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 00:35:43

US3162238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:44
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:49
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:51
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:56
User entered '25 Feb 2021'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:58
User entered empty.	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:00
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:02
User entered '26 Feb 2021'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:04
User entered empty.	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:06
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:08
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:10
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:12
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:14
User entered '1'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:16
User entered '25 Feb 2021'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:18
User entered '26 Feb 2021'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:20
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:22
User entered empty.	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:24
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:25
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:28
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:30
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:32
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:34
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 17:39:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Mar 2021 22:46:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 00:35:43
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:42:58
	(b) (4), (b) (6)	15 Apr 2021 21:49:42
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'other action updated. Other action that has been taken was hospitalization. No con med or con procedure occurred, per CRIO' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 17:40:44
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 17:39:45
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 02:36:31
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Mar 2021 22:46:17
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:49:45
User opened query 'Thank you for your response to the query above, however, please do not respond to this query about updating Con Meds or Con Procedures until you have received hospital medical records. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:54:26
User entered '0'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:47:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:47:53
User entered empty.	Judith Kirstein (b) (4)	12 Mar 2021 00:35:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:48:01
User closed query 'Per DM CLR: Narrative = TONSILLECTOMY AND ADENOIDECTOMY ON 25FEB21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	01 Apr 2021 09:45:15
(Site from DM).	(b) (4), (b) (6)	
Query 'Per DM CLR: Narrative = TONSILLECTOMY AND ADENOIDECTOMY ON 25FEB21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	31 Mar 2021 19:57:09
' answered with 'ConProc has been updated with Tonsillectomy and adenoidectomy, per query request (Site from DM).	(b) (4), (b) (6)	
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.'	(b) (4), (b) (6)	22 Mar 2021 19:04:10
(Site from Safety).	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Narrative = TONSILLECTOMY AND ADENOIDECTOMY ON 25FEB21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	21 Mar 2021 07:02:39
(Site from DM).	(b) (4), (b) (6)	
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.'	Judith Kirstein (b) (4)	20 Mar 2021 22:46:43
answered with 'Subject had negative covid test 2 days before surgery and did not have any covid testing in hospital' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.'	(b) (4), (b) (6)	19 Mar 2021 12:52:48
(Site from Safety).	(b) (4), (b) (6)	

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 12:52:37
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).		19 Mar 2021 12:52:22
User entered 'Subject had planned tonsillectomy and adenoidectomy on 25FEB21 and was noted to be hypoxic after surgery, so admitted overnight, discharged the next day 26FEB21'	Judith Kirstein (b) (4) (b) (4)	12 Mar 2021 00:35:43

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 00:35:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:58:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:45:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:45:53
Data point term sent to Coder	System	12 Mar 2021 03:59:49
User entered 'worsening of obstructive sleep apnea'	Jessica Fisher (b) (4) (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:58:57
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:00
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:03
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:51:43
User closed query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 22:51:40
Query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' answered with 'updated. new information obtained on 20MAR21' (Site from CRA).		13 Apr 2021 17:37:01
User entered '01 Nov 2020' reason for change: New Information		13 Apr 2021 17:36:32
User opened query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' (Site from CRA).		31 Mar 2021 20:58:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Mar 2021 22:45:10
User entered '01 Jan 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Mar 2021 22:45:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 03:58:55
User entered 'UN Jan 2021' (non-conformant).	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:06
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 03:58:55

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Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:09
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:12
User entered '25 Feb 2021'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Generated On: 09 Jun 2021 15:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:18
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:38
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:43
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:45
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:50
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:53
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:55
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:59:57
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:00
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:03
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:06
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:10
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:12
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:19
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:23
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:26
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:29
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).		31 Mar 2021 05:56:58
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'con procedure added' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:46:46
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 07:02:51
User entered 'I'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:34
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:00:36
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 03:58:55

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:26:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:26:51
Data point term sent to Coder	System	12 Mar 2021 04:01:50
User entered 'worsening of recurrent tonsillitis'	Jessica Fisher (b) (4) (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:51:20
User closed query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' (Site from CRA).		14 Apr 2021 22:51:12
Query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' answered with 'updated. new information obtained on 20MAR2021. ' (Site from CRA).		13 Apr 2021 17:35:16
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Apr 2021 17:34:46
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 17:34:46
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Apr 2021 17:33:45
User entered '01 Nov 2021' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 17:33:45
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User opened query 'Per eSource start date is recorded as '01NOV2020'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 21:01:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Mar 2021 22:45:23
User entered '01 Jan 2021' reason for change: New Information	Judith Kirstein (b) (4)	20 Mar 2021 22:45:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Mar 2021 22:10:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Mar 2021 22:10:30
User entered 'UN Jan 2021' (non-conformant).	(b) (4), (b) (6)	17 Mar 2021 22:10:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:23:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:23:43
User entered 'NK Jan 2021' (non-conformant).	Jessica Fisher (b) (4)	14 Mar 2021 20:23:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:23:18

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:23:18
User entered 'UN Jan 2021' (non-conformant).	Jessica Fisher (b) (4)	14 Mar 2021 20:23:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 04:01:03
User entered 'un Jan 21' (non-conformant).	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 04:01:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	13 Apr 2021 17:34:46
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	13 Apr 2021 17:33:45
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:23:18
User entered '25 Feb 2021' reason for change: New Information	Jessica Fisher (b) (4)	14 Mar 2021 20:23:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 04:01:03
User entered '25 Feb 21' (non-conformant).	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Mar 2021 20:23:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Mar 2021 20:23:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Jessica Fisher (b) (4)	14 Mar 2021 20:23:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 04:01:03
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User closed query 'Per DM CLR: Other Action Take = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).		31 Mar 2021 05:57:08
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'con procedure added' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:46:23
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 07:03:03
User entered 'I'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:01:51
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 04:01:03

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:19:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:19:46
Data point term sent to Coder	System	12 Mar 2021 04:03:54
User entered 'pain due to tonsillectomy and adenoidectomy'	Jessica Fisher (b) (4) (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:24:45
User entered '25 Feb 2021' reason for change: New Information	Jessica Fisher (b) (4)	14 Mar 2021 20:24:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 04:03:08
User entered '25 Feb 21' (non-conformant).	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Mar 2021 20:24:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Mar 2021 20:24:45
User entered 'No (N)' reason for change: Data Entry Error	Jessica Fisher (b) (4)	14 Mar 2021 20:24:45
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 04:03:08
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Mar 2021 20:24:45
User entered '01 Mar 2021' reason for change: Data Entry Error	Jessica Fisher (b) (4)	14 Mar 2021 20:24:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Mar 2021 04:03:08
User entered '01 Mar 21' (non-conformant).	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '1'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:02:47
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 04:03:08

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 23:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	24 Mar 2021 23:39:49
Data point term sent to Coder	System	24 Mar 2021 23:39:01
User entered 'Deviated Nasal Septum'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '09 Nov 2020'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:50:44
User closed query 'Per eSource this is marked 'not applicable'. Please reconcile. ' (Site from CRA).		14 Apr 2021 22:50:34
Query 'Per eSource this is marked 'not applicable'. Please reconcile. ' answered with 'data entry error. updated per query ' (Site from CRA).		13 Apr 2021 17:32:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		13 Apr 2021 17:32:11
DataPoint Un-verified.		31 Mar 2021 21:04:09
DataPoint Verified.		31 Mar 2021 21:04:02
User opened query 'Per eSource this is marked 'not applicable'. Please reconcile. ' (Site from CRA).		31 Mar 2021 21:03:49
User entered 'None (NONE)'		24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'I'		24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'		24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered '0'		24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:04:02
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 23:38:52

US3162238

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 23:38:52

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:31:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:24:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:28:15

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
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: RAMIPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:31:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:31:43
Data point term sent to Coder User entered 'RAMIPRIL'	System Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:45 16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 05:02:13
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:02:50
Query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' answered with 'Corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Oct 2020 05:02:24
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 03:45:57
User entered 'hypertension'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '10'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'twice daily (BID)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un UNK 2015'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:30:38

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:32:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:32:45
Data point term sent to Coder User entered 'AMLODIPINE'	System Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:46 16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'hypertension'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '10'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un UNK 2015'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:30:59

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:08:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:08:41
Data point term sent to Coder	System	16 Sep 2020 19:31:47
User entered 'ATORVASTATIN'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'STROKE PREVENTION'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '10'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:31:26

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:33:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:33:48
Data point term sent to Coder User entered 'TRULICITY'	System Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:50 16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'TYPE 2 DIABETES'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0.75'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'every week (QS)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Jun 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Sep 2020 19:32:49

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 19:34:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 19:34:50
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 19:33:52
User entered 'NOVOLOG'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'TYPE 2 DIABETES'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
User closed query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:37:04
Query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' answered with 'correct as is, based on glucose readings, dose per administration varies. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 22:05:00
User opened query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:19:49
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'sliding scale'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Other (OTHER)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'units'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:36:53
DataPoint Un-verified.	Jessica Fisher (b) (4)	13 Jan 2021 13:45:23
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	13 Jan 2021 13:45:23
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:36:55
DataPoint Un-verified.	Jessica Fisher (b) (4)	13 Jan 2021 13:45:23
User entered '01 Dec 2020' reason for change: New Information	Jessica Fisher (b) (4)	13 Jan 2021 13:45:23
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:33:45
	(b) (4)	

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User entered empty.	System	16 Sep 2020 19:33:45

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User entered empty.	System	16 Sep 2020 19:33:45

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:53:48
User entered empty.	System	16 Sep 2020 19:33:45

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:32:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:32:48
Data point term sent to Coder	System	16 Sep 2020 19:34:52
User entered 'ROPINAROLE'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'RESTLESS LEG SYNDROME'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0.5'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un UNK 2018'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:34:14

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM BROMIDE/ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:09:48
Data point term sent to Coder	System	16 Sep 2020 19:36:01
User entered 'IPRATROPIUM BROMIDE/ALBUTEROL SULFATE INHALATION SOLUTION'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mild asthma'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0.5/2.5'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un UNK 2017'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:00

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:36:43
Data point term sent to Coder	System	16 Sep 2020 19:36:01
User entered 'flonase'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Seasonal allergies'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '50'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'ug (ug)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Nasal (NASAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un UNK 2017'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:35:23

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:36:43
Data point term sent to Coder	System	16 Sep 2020 19:36:02
User entered 'vitamin c'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '500'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:35:53

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:37:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:37:44
Data point term sent to Coder	System	16 Sep 2020 19:37:04
User entered 'tumeric'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '500'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:36:47

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:38:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:38:47
Data point term sent to Coder	System	16 Sep 2020 19:38:07
User entered 'Vitamin D'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '5000'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'IU (IU)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:37:10

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:38:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:38:47
Data point term sent to Coder	System	16 Sep 2020 19:38:09
User entered 'calcium'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Nutritional supplement'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '600'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'once daily (QD)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'un Mar 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:27:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:02
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 19:37:30

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
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: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:50:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:50:43
	(b) (4)	
Data point term sent to Coder	System	12 Mar 2021 04:06:55
User entered 'Norco (Hydrocodone Bitartrate/Acetaminophen)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'pain due to tonsillectomy and adenoidectomy'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered '7.5/325'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'mg (mg)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'other (OTHER)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'Q4H'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered empty.	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered '27 Feb 2021'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered '0'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered '01 Mar 2021'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:27:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:57:12
User entered 'No (N)'	Jessica Fisher (b) (4)	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User entered empty.	System	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User entered empty.	System	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:54:05
User entered empty.	System	12 Mar 2021 04:06:03

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:31:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:39
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:55:40
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:01
User entered 'Yes (Y)' reason for change: New Information	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:37:33
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	23 Feb 2021 03:48:38
DataPoint Un-verified.	Jessica Fisher (b) (4)	23 Feb 2021 03:48:17
Signature has been broken.	Jessica Fisher (b) (4)	23 Feb 2021 03:48:17
User entered 'Yes (Y)' reason for change: New Information	Jessica Fisher (b) (4)	23 Feb 2021 03:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:45:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:29:44
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:27:38

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:17

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered '25 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:49

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:17

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered 'Bilateral tonsillectomy'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:49

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:49

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:17

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:44:49

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:17

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered '25 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:45:33

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:17

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered 'Bilateral adenoidectomy'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:45:33

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 04:45:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 04:45:57
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:45:57
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 04:45:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:45:33

US3162238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:17

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:30:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:56:08
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 04:45:33

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'USA-US074-2021-MRNA-1273-P301000019'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Judith'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Kirstein'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'BANNING'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'CA'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '92220'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'US'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 18:56:42
User entered '2'	System	22 Mar 2021 19:02:01
User entered '1'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'USA-US074-2021-MRNA-1273-P301000019'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Judith'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Kirstein'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'BANNING'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'CA'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '92220'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'US'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 18:56:42
User entered '2'	System	22 Mar 2021 19:02:01
User entered '1'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
User entered '12/Mar/2021 10:56'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'USA-US074-2021-MRNA-1273-P301000019'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Judith'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Kirstein'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'BANNING'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'CA'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '92220'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'US'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 18:56:42
User entered '2'	System	22 Mar 2021 19:02:01
User entered '1'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
User entered '22/Mar/2021 12:01'	System	22 Mar 2021 19:02:01

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 19:02:01

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'USA-US074-2021-MRNA-1273-P301000019'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Yes (Y)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'No (N)'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Judith'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'Kirstein'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'BANNING'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered 'CA'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:55:59
User entered '92220'	System	12 Mar 2021 15:55:20

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 18:56:29
User entered 'US'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Apr 2021 18:56:42
User entered '2'	System	22 Mar 2021 19:02:01
User entered '1'	System	12 Mar 2021 15:56:18

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
User entered '14/Apr/2021 14:56'	System	14 Apr 2021 18:56:42

US3162238

Folder: SAE USA-US074-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:31:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:15:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:50:02
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 18:56:42