

US3722158 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:34:43

All time stamps listed in this document are displayed in GMT

US3722158

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:51:49

Generated On: 10 Jun 2021 09:34:43

[Participant ID](#)

US3722158

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

US3722158

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:21:50

Generated On: 10 Jun 2021 09:34:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 21:51:54

Generated On: 10 Jun 2021 09:34:43

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:21:50

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Date of Informed Consent (<i>dd MMM yyyy</i>)	7 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:21:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:21:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:51:55

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	(b) (6) 1976
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)	(b) (6) 1976
Start Year (derived)	1976
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:51:55

Generated On: 10 Jun 2021 09:34:43

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:51:55

Generated On: 10 Jun 2021 09:34:43

Condition	VAGINAL EXCESSIVE BLEEDING
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:51:55

Generated On: 10 Jun 2021 09:34:43

Condition	GRADE 2 HEART MURMUR
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:51:55

Generated On: 10 Jun 2021 09:34:43

Condition	LOWER EXTREMITY EDEMA
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:21:50

Generated On: 10 Jun 2021 09:34:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:04 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:04
Height (<i>xxx.x</i>)	65.5 in
Weight (<i>xxx.x</i>)	277.6 lb
BMI (<i>xxx.x</i>)	45.58760 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) 09 Mar 2021 11:21:50

Generated On: 10 Jun 2021 09:34:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

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Form: Childbearing Potential

Data signed: (b) (4) 09 Mar 2021 11:21:50

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Date of assessment (dd MMM yyyy) 7 AUG 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 2010

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) 09 Mar 2021 11:21:50

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:21:50

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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) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143352

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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)	7 AUG 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:04
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 AUG 2020
Time of assessment (00:00-23:59)	17:23 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 17:23
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 16:53 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 16:53

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) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 AUG 2020
Collection time (00:00-23:59)	16:29 (24 HR)
Collection date and time (derived)	7 AUG 2020 16:29

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:24	7 AUG 2020 16:24
Nasopharyngeal Swab 2	Yes	16:24	7 AUG 2020 16:24

US3722158

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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: 10 Jun 2021 09:34:43

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 17:26

PC Open Date & Time

07 AUG 2020 17:13

PC Close Date & Time

07 AUG 2020 19:43

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	07 AUG 2020 20:40
PC Open Date & Time	07 AUG 2020 20:38
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:55

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	09 AUG 2020 13:25
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

99.0 °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

11 AUG 2020 15:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

98.7 °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

12 AUG 2020 12:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:28

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

07 AUG 2020 17:27

PC Open Date & Time

07 AUG 2020 17:13

PC Close Date & Time

07 AUG 2020 19:43

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

07 AUG 2020 20:41

PC Open Date & Time

07 AUG 2020 20:38

PC Close Date & Time

08 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

08 AUG 2020 15:56

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

09 AUG 2020 13:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

11 AUG 2020 15:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

12 AUG 2020 12:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

13 AUG 2020 12:29

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:28
PC Open Date & Time	07 AUG 2020 17:13
PC Close Date & Time	07 AUG 2020 19:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 20:41
PC Open Date & Time	07 AUG 2020 20:38
PC Close Date & Time	08 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:56
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 13:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 15:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:29
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 15:22
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 8

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 AUG 2020 15:22

PC Open Date and Time 14 AUG 2020 12:00

PC Close Date and Time 15 AUG 2020 11:59

US3722158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:06

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:06

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:06

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:06

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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)	8 SEP 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 09:23
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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)	8 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:32
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3722158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:02

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

US3722158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	10:35 (24 HR)
Collection date and time (derived)	8 SEP 2020 10:35

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	8 SEP 2020 10:40
Nasopharyngeal Swab 2	Yes	10:40	8 SEP 2020 10:40

US3722158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

98.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp

08 SEP 2020 11:53

PC Open Date & Time

08 SEP 2020 11:22

PC Close Date & Time

08 SEP 2020 13:52

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	08 SEP 2020 19:03
PC Open Date & Time	08 SEP 2020 14:47
PC Close Date & Time	09 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:04

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 15:42

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

11 SEP 2020 12:05

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

12 SEP 2020 12:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

98.9 °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

13 SEP 2020 22:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

98.8 °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

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

08 SEP 2020 11:54

PC Open Date & Time

08 SEP 2020 11:22

PC Close Date & Time

08 SEP 2020 13:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

08 SEP 2020 19:04

PC Open Date & Time

08 SEP 2020 14:47

PC Close Date & Time

09 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

09 SEP 2020 12:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

15

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)**

15

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 15:43

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

11 SEP 2020 12:05

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

12 SEP 2020 12:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

13 SEP 2020 22:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:54
PC Open Date & Time	08 SEP 2020 11:22
PC Close Date & Time	08 SEP 2020 13:52

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:04
PC Open Date & Time	08 SEP 2020 14:47
PC Close Date & Time	09 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:44
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

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 ☒

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:01
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3722158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 10:13
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3722158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	5 OCT 2020 10:26

US3722158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:07:15

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 10:58:13

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission 14 OCT 2020 02:17:31

Patient Cloud Open Date & Time 14 OCT 2020 00:01

Patient Cloud Close Date & Time 18 OCT 2020 23:59

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 14:41:01

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 13:23:48

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 12:38:20

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

24 NOV 2020 08:27:30

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

29 NOV 2020 02:49:38

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

10 DEC 2020 09:27:43

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 10:04:58

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

21 DEC 2020 08:42:53

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

29 DEC 2020 11:12:45

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

03 JAN 2021 08:36:32

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

11 JAN 2021 18:50:44

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

17 JAN 2021 11:12:11

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 15:21:25

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 08:50:51

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 FEB 2021 09:24:27
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 13:45:03
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 10:33:40

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 <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	28 FEB 2021 08:31:05
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 09:16:14

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

15 MAR 2021 11:49:22

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 10:27:47

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 MAR 2021 07:59:36
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 APR 2021 13:23:32
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 09:59:46

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 08:55:34

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 08:43:24

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 08:40:00

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 <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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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°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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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°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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 <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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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°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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3722158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:34:43

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 08:31:20

US3722158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:20:19

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:20:19

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:21:55

Generated On: 10 Jun 2021 09:34:43

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	VISIT4
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US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:51:55

Generated On: 10 Jun 2021 09:34:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 14:18
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:21:55

Generated On: 10 Jun 2021 09:34:43

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.

US3722158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:21:50

Generated On: 10 Jun 2021 09:34:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	14:37 (24 HR)
Collection date and time (derived)	22 FEB 2021 14:37

US3722158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:21:50

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722158

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:51:52

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722158

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722158

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:34:43

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"/>

US3722158

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:34:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722158

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3722158

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3722158

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

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

Collection date (dd MMM yyyy)	18 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	16:17 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	18 JAN 2021 16:17
------------------------------------	-------------------

US3722158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00 - 23:59)

16:19

Collection Date and Time (derived)

18 JAN 2021 16:19

US3722158

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

AEID	USA-US083-2021-MRNA-1273-P30 1000012
Adverse event	PERIRECTAL ABSCESS
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)	5 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	28 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

SUBJECT REPORTED TO SITE
ON 26 FEB 2021 THAT SHE
WENT TO THE ER WITH PAIN
AND UNDERWENT REMOVAL
OF AN ABSCESS CAUSED BY
AN ANAL FISTULA ON 25 FEB
2021. SUBJECT EXPECTS TO BE
DISCHARGED ON 27 FEB 2021.
SITE WILL UPDATE ONCE
MEDICAL RECORDS ARE
RECEIVED. SUBJECT
INDICATED ON 01 MAR 2021
THAT SHE WAS DISCHARGED
ON 28 FEB 2021.

RECORDS RECEIVED AND
REVIEWED BY SITE.
MEDICATIONS AND
PROCEDURES UPDATED.
SUBJECT WAS DISCHARGED ON
2-28-2021 AFTER HAVING AN
INCISION AND DRAINAGE OF
THE ABSCESS, LITHOTOMY,
AND PLACEMENT OF SETON.
SUBJECT HAD A CT DONE
WHERE THE ABSCESS WAS
IDENTIFIED AND LABS WERE
DRAWN. WBC WAS 22.1 ON
2-25-2021. NO REFERENCE
RANGES PROVIDED IN
RECORDS.
NO COVID TESTING NOTED IN
RECORDS. TITLE OF SAE
CHANGED TO REFLECT
MEDICAL RECORDS.

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

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

AEID	
Adverse event	ANAL FISTULA
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 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

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 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	

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

SUBJECT WAS ADMITTED TO
HOSPITAL ON 25 FEB 2021 FOR
AN ABSCESS RELATED TO AN
ANAL FISTULA. SUBJECT
REPORTS SHE WAS
DISCHARGED ON 28 FEB 2021.
SITE IS PENDING MEDICAL
RECORDS. UPON RECEIVING
MEDICAL RECORDS, THIS
EVENT IS NO LONGER
CONSIDERED SERIOUS.

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)	0

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

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

Yes ☒

No ☐

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

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE SINUSITIS

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 (3)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	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)		02 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)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COVID LIKE SYMPTOMS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication COVID LIKE SYMPTOMS

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 (5)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	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)	26 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)		28 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication CLEOCIN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication CLEOCIN

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 900

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		28 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication DESMOPRESSIN ACETATE
(DDAVP, STIMATE)

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 47.16

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 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)		28 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication DESMOPRESSIN ACETATE
(DDAVP, STIMATE)

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 35.36

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication DIATRIZOATE
MEG-DIATRIZOATE SOD

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 66-10

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

If dose unit is Other, specify PER CENT

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		28 FEB 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"/>

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

Name of Medication FENTANYL CITRATE

Prophylaxis Yes ☐
No ☒

Indication PERIRECTAL ABSCESS

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)

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:51:50

Generated On: 10 Jun 2021 09:34:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 FEB 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"/>

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 FEB 2021	INCISION AND DRAINAGE OF PERIRECTAL ABSCESS	Adverse Event	
25 FEB 2021	LITHOTOMY	Adverse Event	
25 FEB 2021	PLACEMENT OF SETON	Adverse Event	

US3722158

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:34:43

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

US3722158

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:34:43

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 ☐

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/MAR/2021 15:11
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

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:15
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

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 12:32
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

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:53
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

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 10:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:51:51

Generated On: 10 Jun 2021 09:34:43

SAEID	USA-US083-2021-MRNA-1273-P301000012
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/APR/2021 09:11
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

US3722158 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722158

Form: Participant Creation

Generated On: 10 Jun 2021 09:34:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'US3722158'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:54:08

US3722158

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:56:44

US3722158

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:54:09

US3722158

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	07 Aug 2020 20:56:44

US3722158

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'SCRN'	System	07 Aug 2020 20:56:44

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:54:11

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '45'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'YEARS'	System	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '45'	System	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Female (F)'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:00:49
Signature has been broken.	Marlee Smith (b) (4)	30 Mar 2021 12:40:37
User entered 'Hispanic or Latino (HISPANIC OR LATINO)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Marlee Smith (b) (4)	30 Mar 2021 12:40:37
	(b) (4)	
	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4)	07 Aug 2020 20:57:02
	(b) (4)	

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'I'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:34:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:12:06
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:57:02

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '7 Aug 2020'	Amy Ford (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Aug 2020'	System	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2020'	System	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:10:37
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:55:45
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:55:40
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 08:21:00
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:57:16

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:54:09

US3722158

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:34:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'I'	System	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:34:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 20:57:47

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
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)	07 Aug 2020 20:59:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 20:59:50
Data point term sent to Coder	System	07 Aug 2020 20:58:16
User entered 'Seasonal allergies'	Kayla Peay (b) (4)	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	07 Aug 2020 20:58:23
User entered (b) (6) 1976' reason for change: Data Entry Error	Kayla Peay (b) (4)	07 Aug 2020 20:58:23
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	07 Aug 2020 20:58:09
User entered (b) (6) 1975'	System	07 Aug 2020 20:58:09
	Kayla Peay (b) (4)	07 Aug 2020 20:58:09
	(b) (4)	

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered (b) (6) 1976'	System	07 Aug 2020 20:58:23
User entered (b) (6) 1975'	System	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '1976'	System	07 Aug 2020 20:58:23
User entered '1975'	System	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Aug 2020 20:58:09

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:21:22
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 15:02:25
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 13:00:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 15:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 15:05:44
Data point term sent to Coder	System	25 Sep 2020 15:05:14
User entered 'hysterectomy'	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'un UNK 2010'	Kayla Peay (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Kayla Peay (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Kayla Peay (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Jan 2010'	System	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2010'	System	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:17:15
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 13:00:27
User entered empty.	System	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	25 Sep 2020 15:04:25

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal disorders NEC, PT: Vaginal haemorrhage, LLT: Vaginal bleeding - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 18:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 18:41:38
Data point term sent to Coder	System	10 Nov 2020 18:41:03
User closed query 'For coding purposes, please specify the body location of the EXCESSIVE BLEEDING and update the term with your response' (Site from System).	System	10 Nov 2020 18:40:38
Query 'For coding purposes, please specify the body location of the EXCESSIVE BLEEDING and update the term with your response' answered with 'updated' (Site from System).	Marlee Smith (b) (4)	10 Nov 2020 18:40:38
Coding entries removed.	Marlee Smith (b) (4)	10 Nov 2020 18:40:33
User entered 'vaginal EXCESSIVE BLEEDING' reason for change: Data Entry Error	Marlee Smith (b) (4)	10 Nov 2020 18:40:33
User opened query 'For coding purposes, please specify the body location of the EXCESSIVE BLEEDING and update the term with your response' (Site from System).	Coder Import (b) (4)	29 Oct 2020 18:16:47
User coded data point as SOC: Investigations, HLGT: Haematology investigations (incl blood groups), HLT: Coagulation and bleeding analyses, PT: Bleeding time prolonged, LLT: Bleeding time increased - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 15:03:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 15:03:33
Data point term sent to Coder	System	21 Oct 2020 15:03:03
User entered 'Excessive bleeding'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'UN UNK 2010'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'UN UNK 2010'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Jan 2010'	System	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2010'	System	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Jan 2010'	System	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2010'	System	21 Oct 2020 15:02:58

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:00:49
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:10:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:10:56
Data point term sent to Coder	System	07 Apr 2021 18:11:20
User entered 'Grade 2 heart murmur'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'un UNK 2000'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Yes (Y)'	Marlee Smith (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Jan 2000'	System	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2000'	System	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Apr 2021 18:10:43

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:00:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:12:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:12:44
Data point term sent to Coder	System	07 Apr 2021 18:11:20
User entered 'lower extremity edema'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'un UNK 2004'	Marlee Smith (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Yes (Y)'	Marlee Smith (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Jan 2004'	System	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '2004'	System	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:15:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:11:56
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	System	07 Apr 2021 18:10:59

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '7 Aug 2020'	(b) (4) Kayla Peay (b) (4) (b) (4)	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '16:04'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '7 Aug 2020 16:04'	System	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '65.5' in	(b) (4) Kayla Peay (b) (4)	07 Aug 2020 20:59:17
DataPoint set to visible.	(b) (4) System	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '277.6' lb	(b) (4) Kayla Peay (b) (4)	07 Aug 2020 20:59:17
DataPoint set to visible.	(b) (4) System	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
Amendment Manager: User entered '45.58760'	System	16 Sep 2020 23:48:08
User entered '45.6'	System	07 Aug 2020 20:59:17
DataPoint set to visible.	System	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'kg/m2'	System	07 Aug 2020 20:59:17
DataPoint set to visible.	System	07 Aug 2020 20:57:23

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:43
User entered '98' F	Kayla Peay (b) (4)	07 Aug 2020 20:59:17
	(b) (4)	

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:16:43
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:43
User entered '78'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17
	(b) (4)	

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'bpm'	System	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:43
User entered '16'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17
	(b) (4)	

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'breaths/min'	System	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:43
User entered '107'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17
	(b) (4)	

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'mmHg'	System	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:43
User entered '63'	Kayla Peay (b) (4)	07 Aug 2020 20:59:17
	(b) (4)	

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'mmHg'	System	07 Aug 2020 20:59:17

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49

US3722158

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49

US3722158

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 20:59:23

US3722158

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:55:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 15:21:07
User entered '7 Aug 2020'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 20:59:23

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '7 Aug 2020'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Surgically sterile (SURGICALLY STERILE)'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'UN UNK 2010'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:34:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Kayla Peay (b) (4)	07 Aug 2020 21:00:05

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	(b) (4) Amy Ford (b) (4) (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	(b) (4) Amy Ford (b) (4) (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	(b) (4) Amy Ford (b) (4) (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

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)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'I'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '0'	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:58:01

US3722158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:58:16

US3722158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020'	Amy Ford (b) (4)	07 Aug 2020 20:58:16

US3722158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	07 Aug 2020 20:58:16

US3722158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'VISIT1'	System	07 Aug 2020 20:58:16

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:15

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:59:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:59:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 20:44:15
User entered '143352' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:15

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 20:44:15

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

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)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:35

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

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)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:35

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Per CDM: Response noted, 'not been diagnosed with Severe Obesity'. However BMI at screening vital signs form is recorded as 45.5 kg/m2 and also response to this field is recorded as Yes. Please verify the data recorded if correct update the obesity details in MH page, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 06:54:27
Query 'Per CDM: Response noted, 'not been diagnosed with Severe Obesity'. However BMI at screening vital signs form is recorded as 45.5 kg/m2 and also response to this field is recorded as Yes. Please verify the data recorded if correct update the obesity details in MH page, else clarify.' answered with 'Subject has not been medically diagnosed with severe obesity. If staff were to enter this diagnosis in medical history, there is no where to write a comment explaining it is not a medical diagnosis. ' (Site from DM).	Marlee Smith (b) (4) (b) (4)	18 Feb 2021 16:11:46
User opened query 'Per CDM: Response noted, 'not been diagnosed with Severe Obesity'. However BMI at screening vital signs form is recorded as 45.5 kg/m2 and also response to this field is recorded as Yes. Please verify the data recorded if correct update the obesity details in MH page, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:31:52
User closed query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:31:52
Query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' answered with 'Subject has not been diagnosed with Severe Obesity. ' (Site from DM).	Marlee Smith (b) (4) (b) (4)	11 Jan 2021 19:22:58

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 18:14:31
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	07 Aug 2020 20:58:35

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:35

US3722158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'No (N)'	Amy Ford (b) (4)	07 Aug 2020 20:58:35

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:16:53
User entered '65.5' in reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:16:53
User entered '277.6' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:53
User entered '65.5' in reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:16:53
User entered '277.6' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered 'No (N)'	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16:04' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 16:04'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '98' F reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '78' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	07 Aug 2020 21:01:22
	(b) (4)	

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'bpm'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'breaths/min'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '107' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '63' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 17:16:53
User entered '65.5' in reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:16:53
User entered '277.6' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered 'No (N)'	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 14:08:31
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 15:08:50
User entered '17:23' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 17:23'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '98' F reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '77' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'bpm'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '17' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	07 Aug 2020 21:01:22
	(b) (4)	

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'breaths/min'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '110' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '62' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:08:50
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	12 Aug 2020 15:08:50
User entered empty.	System	07 Aug 2020 21:01:22

US3722158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:17:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:07:04
User entered 'No (N)'	Kayla Peay (b) (4)	07 Aug 2020 21:01:15

US3722158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 17:17:00
User entered '7 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:07:04
User entered empty.	Kayla Peay (b) (4)	07 Aug 2020 21:01:15

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020'	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16:53'	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 16:53'	System	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4)	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'ONCE'	System	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 20:59:03

US3722158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 21:01:47

US3722158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020'	Kayla Peay (b) (4)	07 Aug 2020 21:01:47

US3722158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16:29'	Kayla Peay (b) (4)	07 Aug 2020 21:01:47

US3722158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 16:29'	System	07 Aug 2020 21:01:47

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:34:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '7 Aug 2020'	Kayla Peay (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16:24'	Kayla Peay (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 16:24'	System	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '16:24'	Kayla Peay (b) (4)	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '7 Aug 2020 16:24'	System	07 Aug 2020 21:02:07

US3722158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Aug 2020 21:01:06

US3722158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	07 Aug 2020 21:01:06

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:25:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9b56e68-1378-4b00-a182-e40f8a13137d'	System	07 Aug 2020 21:26:16
User entered 'Yes (Y)'	System	07 Aug 2020 21:26:16

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:25:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9b56e68-1378-4b00-a182-e40f8a13137d' User entered '98.0'	System	07 Aug 2020 21:26:16
	System	07 Aug 2020 21:26:16

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:25:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9b56e68-1378-4b00-a182-e40f8a13137d'	System	07 Aug 2020 21:26:16
User entered 'No (N)'	System	07 Aug 2020 21:26:16

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:26:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9b56e68-1378-4b00-a182-e40f8a13137d'	System	07 Aug 2020 21:26:16
User entered '07 Aug 2020 17:26'	System	07 Aug 2020 21:26:16

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 17:13'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 19:43'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:39:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cb3e400a-b242-447f-b7a7-ee07d8d8e8e5'	System	08 Aug 2020 00:40:48
User entered 'Yes (Y)'	System	08 Aug 2020 00:40:48

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:40:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cb3e400a-b242-447f-b7a7-ee07d8d8e8e5'	System	08 Aug 2020 00:40:48
User entered '98.0'	System	08 Aug 2020 00:40:48

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:40:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cb3e400a-b242-447f-b7a7-ee07d8d8e8e5'	System	08 Aug 2020 00:40:48
User entered 'No (N)'	System	08 Aug 2020 00:40:48

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:40:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cb3e400a-b242-447f-b7a7-ee07d8d8e8e5'	System	08 Aug 2020 00:40:48
User entered '07 Aug 2020 20:40'	System	08 Aug 2020 00:40:48

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 20:38'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 2'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:55:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '76758b6f-c4ee-4be5-accc-f9bcfd5dccab'	System	08 Aug 2020 19:55:54
User entered 'Yes (Y)'	System	08 Aug 2020 19:55:54

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:55:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '76758b6f-c4ee-4be5-accf-f9bcfd5dccab'	System	08 Aug 2020 19:55:54
User entered '97.5'	System	08 Aug 2020 19:55:54

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:55:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '76758b6f-c4ee-4be5-accf-f9bcfd5dccab'	System	08 Aug 2020 19:55:54
User entered 'No (N)'	System	08 Aug 2020 19:55:54

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:55:52', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '76758b6f-c4ee-4be5-accc-f9bcfd5dccab'	System	08 Aug 2020 19:55:54
User entered '08 Aug 2020 15:55'	System	08 Aug 2020 19:55:54

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 3'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d'	System	09 Aug 2020 17:25:47
User entered 'Yes (Y)'	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d' User entered '97.5'	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d'	System	09 Aug 2020 17:25:47
User entered 'Yes (Y)'	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 12:39:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d'	Amy Ford (b) (4)	17 Aug 2020 17:06:23
User entered '1'	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d' User entered '0'	System	09 Aug 2020 17:25:47
	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:47', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7acdd5b9-9b32-489c-8241-cb3b0781793d' User entered '09 Aug 2020 13:25'	System	09 Aug 2020 17:25:47
	System	09 Aug 2020 17:25:47

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 4'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 5'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:28:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '139b21d3-7dff-47e7-baf1-8ecd170b6f40'	System	11 Aug 2020 19:28:59
User entered 'Yes (Y)'	System	11 Aug 2020 19:28:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:28:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '139b21d3-7dff-47e7-baf1-8ecd170b6f40'	System	11 Aug 2020 19:28:59
User entered '99.0'	System	11 Aug 2020 19:28:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:28:54', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '139b21d3-7dff-47e7-baf1-8ecd170b6f40'	System	11 Aug 2020 19:28:59
User entered 'No (N)'	System	11 Aug 2020 19:28:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:28:57', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '139b21d3-7dff-47e7-baf1-8ecd170b6f40'	System	11 Aug 2020 19:28:59
User entered '11 Aug 2020 15:28'	System	11 Aug 2020 19:28:59

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 6'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ad518fde-8420-49ff-8ae7-91844e0d8cae'	System	12 Aug 2020 16:02:46
User entered 'Yes (Y)'	System	12 Aug 2020 16:02:46

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ad518fde-8420-49ff-8ae7-91844e0d8cae'	System	12 Aug 2020 16:02:46
User entered '98.7'	System	12 Aug 2020 16:02:46

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ad518fde-8420-49ff-8ae7-91844e0d8cae'	System	12 Aug 2020 16:02:46
User entered 'No (N)'	System	12 Aug 2020 16:02:46

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:45', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ad518fde-8420-49ff-8ae7-91844e0d8cae'	System	12 Aug 2020 16:02:46
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 16:02:46

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 7'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:28:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '52693c50-3c3f-4100-923f-42cdefcd3bee'	System	13 Aug 2020 16:28:58
User entered 'Yes (Y)'	System	13 Aug 2020 16:28:58

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:28:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '52693c50-3c3f-4100-923f-42cdefcd3bee'	System	13 Aug 2020 16:28:58
User entered '97.9'	System	13 Aug 2020 16:28:58

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:28:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '52693c50-3c3f-4100-923f-42cdefcd3bee'	System	13 Aug 2020 16:28:58
User entered 'No (N)'	System	13 Aug 2020 16:28:58

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:28:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '52693c50-3c3f-4100-923f-42cdefcd3bee'	System	13 Aug 2020 16:28:58
User entered '13 Aug 2020 12:28'	System	13 Aug 2020 16:28:58

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:26:56', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ac3b9ad9-14cd-44e2-9bb8-8d64d3bd0251'	System	07 Aug 2020 21:27:33
User entered 'None (1)'	System	07 Aug 2020 21:27:33

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ac3b9ad9-14cd-44e2-9bb8-8d64d3bd0251'	System	07 Aug 2020 21:27:33
User entered 'No (N)'	System	07 Aug 2020 21:27:33

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ac3b9ad9-14cd-44e2-9bb8-8d64d3bd0251'	System	07 Aug 2020 21:27:33
User entered 'No (N)'	System	07 Aug 2020 21:27:33

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ac3b9ad9-14cd-44e2-9bb8-8d64d3bd0251'	System	07 Aug 2020 21:27:33
User entered 'None (1)'	System	07 Aug 2020 21:27:33

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:27', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ac3b9ad9-14cd-44e2-9bb8-8d64d3bd0251'	System	07 Aug 2020 21:27:33
User entered '07 Aug 2020 17:27'	System	07 Aug 2020 21:27:33

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 17:13'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 19:43'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:40:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f02a3ac8-183b-4613-adbc-6cefa92dc67e'	System	08 Aug 2020 00:41:13
User entered 'None (1)'	System	08 Aug 2020 00:41:13

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:40:54', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f02a3ac8-183b-4613-adbc-6cefa92dc67e'	System	08 Aug 2020 00:41:13
User entered 'No (N)'	System	08 Aug 2020 00:41:13

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f02a3ac8-183b-4613-adbc-6cefa92dc67e'	System	08 Aug 2020 00:41:13
User entered 'No (N)'	System	08 Aug 2020 00:41:13

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f02a3ac8-183b-4613-adbc-6cefa92dc67e'	System	08 Aug 2020 00:41:13
User entered 'None (1)'	System	08 Aug 2020 00:41:13

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:09', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f02a3ac8-183b-4613-adbc-6cefa92dc67e'	System	08 Aug 2020 00:41:13
User entered '07 Aug 2020 20:41'	System	08 Aug 2020 00:41:13

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 20:38'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 2'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3e132fa8-03b3-4d65-8dbe-2dd1966c9f8f'	System	08 Aug 2020 19:56:21
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 19:56:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:08', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3e132fa8-03b3-4d65-8dbe-2dd1966c9f8f'	System	08 Aug 2020 19:56:21
User entered 'No (N)'	System	08 Aug 2020 19:56:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3e132fa8-03b3-4d65-8dbe-2dd1966c9f8f'	System	08 Aug 2020 19:56:21
User entered 'No (N)'	System	08 Aug 2020 19:56:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3e132fa8-03b3-4d65-8dbe-2dd1966c9f8f'	System	08 Aug 2020 19:56:21
User entered 'None (1)'	System	08 Aug 2020 19:56:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3e132fa8-03b3-4d65-8dbe-2dd1966c9f8f'	System	08 Aug 2020 19:56:21
User entered '08 Aug 2020 15:56'	System	08 Aug 2020 19:56:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 3'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b4ecb3b6-ac09-4248-ad5f-c3176fd9b080'	System	09 Aug 2020 17:26:17
User entered 'None (1)'	System	09 Aug 2020 17:26:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:25:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b4ecb3b6-ac09-4248-ad5f-c3176fd9b080'	System	09 Aug 2020 17:26:17
User entered 'No (N)'	System	09 Aug 2020 17:26:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b4ecb3b6-ac09-4248-ad5f-c3176fd9b080'	System	09 Aug 2020 17:26:17
User entered 'No (N)'	System	09 Aug 2020 17:26:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:08', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b4ecb3b6-ac09-4248-ad5f-c3176fd9b080'	System	09 Aug 2020 17:26:17
User entered 'None (1)'	System	09 Aug 2020 17:26:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b4ecb3b6-ac09-4248-ad5f-c3176fd9b080'	System	09 Aug 2020 17:26:17
User entered '09 Aug 2020 13:26'	System	09 Aug 2020 17:26:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 4'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 5'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:03', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eb11c52d-e3dc-447a-bb75-06cd9d1e3007'	System	11 Aug 2020 19:29:21
User entered 'None (1)'	System	11 Aug 2020 19:29:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eb11c52d-e3dc-447a-bb75-06cd9d1e3007'	System	11 Aug 2020 19:29:21
User entered 'No (N)'	System	11 Aug 2020 19:29:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eb11c52d-e3dc-447a-bb75-06cd9d1e3007'	System	11 Aug 2020 19:29:21
User entered 'No (N)'	System	11 Aug 2020 19:29:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eb11c52d-e3dc-447a-bb75-06cd9d1e3007'	System	11 Aug 2020 19:29:21
User entered 'None (1)'	System	11 Aug 2020 19:29:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:18', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eb11c52d-e3dc-447a-bb75-06cd9d1e3007'	System	11 Aug 2020 19:29:21
User entered '11 Aug 2020 15:29'	System	11 Aug 2020 19:29:21

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 6'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2ec8a8c5-a1b6-4f2e-b5d3-dee312db8573'	System	12 Aug 2020 16:03:08
User entered 'None (1)'	System	12 Aug 2020 16:03:08

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:54', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2ec8a8c5-a1b6-4f2e-b5d3-dee312db8573'	System	12 Aug 2020 16:03:08
User entered 'No (N)'	System	12 Aug 2020 16:03:08

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:57', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2ec8a8c5-a1b6-4f2e-b5d3-dee312db8573'	System	12 Aug 2020 16:03:08
User entered 'No (N)'	System	12 Aug 2020 16:03:08

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:02:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2ec8a8c5-a1b6-4f2e-b5d3-dee312db8573'	System	12 Aug 2020 16:03:08
User entered 'None (1)'	System	12 Aug 2020 16:03:08

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2ec8a8c5-a1b6-4f2e-b5d3-dee312db8573'	System	12 Aug 2020 16:03:08
User entered '12 Aug 2020 12:03'	System	12 Aug 2020 16:03:08

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 7'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ff71ccd-4d16-47d7-aa64-835def1a048f'	System	13 Aug 2020 16:29:17
User entered 'None (1)'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ff71ccd-4d16-47d7-aa64-835def1a048f'	System	13 Aug 2020 16:29:17
User entered 'No (N)'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:08', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ff71ccd-4d16-47d7-aa64-835def1a048f'	System	13 Aug 2020 16:29:17
User entered 'No (N)'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ff71ccd-4d16-47d7-aa64-835def1a048f'	System	13 Aug 2020 16:29:17
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:15', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ff71ccd-4d16-47d7-aa64-835def1a048f'	System	13 Aug 2020 16:29:17
User entered '13 Aug 2020 12:29'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:54', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'None (0)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:27:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered 'No (N)'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T17:28:02', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '71ec4d02-a95e-4d6a-9984-7073e923ecc7'	System	07 Aug 2020 21:28:06
User entered '07 Aug 2020 17:28'	System	07 Aug 2020 21:28:06

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 17:13'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 19:43'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'None (0)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:36', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'None (0)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'None (0)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'None (0)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'None (0)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:52', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered 'No (N)'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-07T20:41:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e99f7ec0-8f26-40ef-9827-a2bbf9b95cc2'	System	08 Aug 2020 00:41:59
User entered '07 Aug 2020 20:41'	System	08 Aug 2020 00:41:59

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '07 Aug 2020 20:38'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 2'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered 'None (0)'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered 'None (0)'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1' User entered 'None (0)'	System	08 Aug 2020 19:56:53
	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1' User entered 'None (0)'	System	08 Aug 2020 19:56:53
	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered 'None (0)'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered 'None (0)'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:49', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered 'No (N)'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-08T15:56:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e2b0a660-6e48-4ce1-be15-5305a7f345c1'	System	08 Aug 2020 19:56:53
User entered '08 Aug 2020 15:56'	System	08 Aug 2020 19:56:53

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 3'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'Some interference with activity (2)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'None (0)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'Some interference with activity (2)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'None (0)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:26:58', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'None (0)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:27:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered 'No (N)'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-09T13:27:18', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd88470df-0c1b-4a15-b05f-99deaf936b83'	System	09 Aug 2020 17:27:18
User entered '09 Aug 2020 13:27'	System	09 Aug 2020 17:27:18

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 4'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 5'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'Some interference with activity (2)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:52', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'None (0)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'None (0)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:29:58', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered 'No (N)'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-11T15:30:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '543ecfdc-5009-4478-946e-27626904e95d'	System	11 Aug 2020 19:30:04
User entered '11 Aug 2020 15:30'	System	11 Aug 2020 19:30:04

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 6'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'None (0)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'None (0)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'None (0)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'No interference with activity (1)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:26', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'None (0)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'None (0)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered 'No (N)'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-12T12:03:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '702042f9-8014-46d9-9e24-c1235f3c8694'	System	12 Aug 2020 16:03:37
User entered '12 Aug 2020 12:03'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 7'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:24', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:26', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:29', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'None (0)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered 'No (N)'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-13T12:29:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '60b2687d-625a-4599-90fa-04a175cfd524'	System	13 Aug 2020 16:29:43
User entered '13 Aug 2020 12:29'	System	13 Aug 2020 16:29:43

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	12 Aug 2020 16:03:37
User entered 'Day 8'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-14T15:22:09', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '4063e8b4-23eb-4740-aa54-75a068a32ee1'	System	14 Aug 2020 19:22:16
User entered 'No (N)'	System	14 Aug 2020 19:22:16

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-14T15:22:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '4063e8b4-23eb-4740-aa54-75a068a32ee1'	System	14 Aug 2020 19:22:16
User entered '14 Aug 2020 15:22'	System	14 Aug 2020 19:22:16

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:03:37

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	13 Aug 2020 16:29:17
User entered 'Day 8'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-14T15:22:18', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '68410301-e2d5-482a-8795-b2e56294b88a'	System	14 Aug 2020 19:22:23
User entered 'None (1)'	System	14 Aug 2020 19:22:23

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-08-14T15:22:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '68410301-e2d5-482a-8795-b2e56294b88a'	System	14 Aug 2020 19:22:23
User entered '14 Aug 2020 15:22'	System	14 Aug 2020 19:22:23

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:29:17

US3722158

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:29:17

US3722158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Amy Ford (b) (4)	14 Aug 2020 19:50:27

US3722158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '14 Aug 2020'	Amy Ford (b) (4)	14 Aug 2020 19:50:27

US3722158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	14 Aug 2020 19:50:27

US3722158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Amy Ford (b) (4)	14 Aug 2020 19:50:27

US3722158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Amy Ford (b) (4)	14 Aug 2020 19:50:33

US3722158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	14 Aug 2020 19:50:33

US3722158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Yes (Y)'	Sara Poff (b) (4)	23 Aug 2020 18:03:41

US3722158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered '23 Aug 2020'	Sara Poff (b) (4)	23 Aug 2020 18:03:41

US3722158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Contact Made (CONTACT MADE)'	Sara Poff (b) (4)	23 Aug 2020 18:03:41

US3722158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered empty.	Sara Poff (b) (4)	23 Aug 2020 18:03:41

US3722158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Yes (Y)'	Sara Poff (b) (4)	23 Aug 2020 18:03:48

US3722158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	23 Aug 2020 18:03:48

US3722158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Yes (Y)'	Kayla Peay (b) (4)	04 Sep 2020 17:52:39

US3722158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered '31 Aug 2020'	Kayla Peay (b) (4)	04 Sep 2020 17:52:39

US3722158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	04 Sep 2020 17:52:39

US3722158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered empty.	Kayla Peay (b) (4)	04 Sep 2020 17:52:39

US3722158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:06
User entered 'Yes (Y)'	Kayla Peay (b) (4)	04 Sep 2020 17:52:46

US3722158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	04 Sep 2020 17:52:46

US3722158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 15:21:07

US3722158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Sara Poff (b) (4)	08 Sep 2020 15:21:07

US3722158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	08 Sep 2020 15:21:07

US3722158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'VISIT2'	System	08 Sep 2020 15:21:07

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '09:23'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 09:23'	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '98.8' F	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '78'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'bpm'	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	08 Sep 2020 16:31:17
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	08 Sep 2020 16:31:17
User entered '19' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	08 Sep 2020 14:32:39
User entered '79'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39
	(b) (4)	

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'breaths/min'	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '123'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '78'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '11:32' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 11:32'	System	08 Sep 2020 16:31:17
User entered empty.	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '98.5' F reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '73' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39
	(b) (4)	

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'bpm'	System	08 Sep 2020 16:31:17
User entered empty.	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39
	(b) (4)	

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'breaths/min'	System	08 Sep 2020 16:31:17
User entered empty.	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '133' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	08 Sep 2020 16:31:17
User entered empty.	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 16:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:31:17
User entered '87' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 16:31:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 14:32:39
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 14:32:39
	(b) (4)	

US3722158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	08 Sep 2020 16:31:17
User entered empty.	System	08 Sep 2020 14:32:39

US3722158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 14:32:47

US3722158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 14:32:47

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '11:02'	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 11:02'	System	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'ONCE'	System	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:21:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 16:31:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 16:31:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '10:35'	Kayla Peay (b) (4)	08 Sep 2020 16:31:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 10:35'	System	08 Sep 2020 16:31:34

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:34:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '10:40'	Kayla Peay (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 10:40'	System	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '10:40'	Kayla Peay (b) (4)	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '8 Sep 2020 10:40'	System	08 Sep 2020 16:31:48

US3722158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 15:21:41

US3722158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	08 Sep 2020 15:21:41

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:53:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '129e06a3-3fdd-49ea-a5fa-10b1b1a3d064'	System	08 Sep 2020 15:53:55
User entered 'Yes (Y)'	System	08 Sep 2020 15:53:55

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:53:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '129e06a3-3fdd-49ea-a5fa-10b1b1a3d064'	System	08 Sep 2020 15:53:55
User entered '98.5'	System	08 Sep 2020 15:53:55

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:53:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '129e06a3-3fdd-49ea-a5fa-10b1b1a3d064'	System	08 Sep 2020 15:53:55
User entered 'No (N)'	System	08 Sep 2020 15:53:55

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:53:53', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '129e06a3-3fdd-49ea-a5fa-10b1b1a3d064'	System	08 Sep 2020 15:53:55
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 15:53:55

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:03:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe184b3a-7b54-4a51-8aba-2cc73061548b'	System	08 Sep 2020 23:03:59
User entered 'Yes (Y)'	System	08 Sep 2020 23:03:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:03:37', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe184b3a-7b54-4a51-8aba-2cc73061548b' User entered '97.9'	System	08 Sep 2020 23:03:59
	System	08 Sep 2020 23:03:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:03:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe184b3a-7b54-4a51-8aba-2cc73061548b'	System	08 Sep 2020 23:03:59
User entered 'No (N)'	System	08 Sep 2020 23:03:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:03:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe184b3a-7b54-4a51-8aba-2cc73061548b'	System	08 Sep 2020 23:03:59
User entered '08 Sep 2020 19:03'	System	08 Sep 2020 23:03:59

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 2'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '75337d48-4ec2-447e-973f-fbbf50c3b19d'	System	09 Sep 2020 16:05:32
User entered 'Yes (Y)'	System	09 Sep 2020 16:05:32

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '75337d48-4ec2-447e-973f-fbbf50c3b19d' User entered '97.9'	System	09 Sep 2020 16:05:32
	System	09 Sep 2020 16:05:32

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:25', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '75337d48-4ec2-447e-973f-fbbf50c3b19d'	System	09 Sep 2020 16:05:32
User entered 'No (N)'	System	09 Sep 2020 16:05:32

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '75337d48-4ec2-447e-973f-fbbf50c3b19d'	System	09 Sep 2020 16:05:32
User entered '09 Sep 2020 12:04'	System	09 Sep 2020 16:05:32

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 3'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:42:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7f62d0b8-c5c9-47fc-a037-93430d244355'	System	10 Sep 2020 19:43:05
User entered 'Yes (Y)'	System	10 Sep 2020 19:43:05

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:42:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7f62d0b8-c5c9-47fc-a037-93430d244355'	System	10 Sep 2020 19:43:05
User entered '99.7'	System	10 Sep 2020 19:43:05

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:42:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7f62d0b8-c5c9-47fc-a037-93430d244355'	System	10 Sep 2020 19:43:05
User entered 'No (N)'	System	10 Sep 2020 19:43:05

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:42:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7f62d0b8-c5c9-47fc-a037-93430d244355'	System	10 Sep 2020 19:43:05
User entered '10 Sep 2020 15:42'	System	10 Sep 2020 19:43:05

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 4'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:04:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd6b01920-7ca0-4767-bae1-b0ad5d214ae2'	System	11 Sep 2020 16:07:44
User entered 'Yes (Y)'	System	11 Sep 2020 16:07:44

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd6b01920-7ca0-4767-bae1-b0ad5d214ae2'	System	11 Sep 2020 16:07:44
User entered '98.7'	System	11 Sep 2020 16:07:44

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:22', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd6b01920-7ca0-4767-bae1-b0ad5d214ae2'	System	11 Sep 2020 16:07:44
User entered 'No (N)'	System	11 Sep 2020 16:07:44

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:25', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd6b01920-7ca0-4767-bae1-b0ad5d214ae2'	System	11 Sep 2020 16:07:44
User entered '11 Sep 2020 12:05'	System	11 Sep 2020 16:07:44

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 5'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:15:53', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f58420b-5c9e-4ab2-9c92-c0b473d26490'	System	12 Sep 2020 16:17:47
User entered 'Yes (Y)'	System	12 Sep 2020 16:17:47

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f58420b-5c9e-4ab2-9c92-c0b473d26490'	System	12 Sep 2020 16:17:47
User entered '97.8'	System	12 Sep 2020 16:17:47

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f58420b-5c9e-4ab2-9c92-c0b473d26490'	System	12 Sep 2020 16:17:47
User entered 'No (N)'	System	12 Sep 2020 16:17:47

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f58420b-5c9e-4ab2-9c92-c0b473d26490'	System	12 Sep 2020 16:17:47
User entered '12 Sep 2020 12:16'	System	12 Sep 2020 16:17:47

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 6'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cff7f4d8-1fda-4b13-96c0-9394d08d7d22'	System	14 Sep 2020 02:02:26
User entered 'Yes (Y)'	System	14 Sep 2020 02:02:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cff7f4d8-1fda-4b13-96c0-9394d08d7d22'	System	14 Sep 2020 02:02:26
User entered '98.9'	System	14 Sep 2020 02:02:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:19', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cff7f4d8-1fda-4b13-96c0-9394d08d7d22'	System	14 Sep 2020 02:02:26
User entered 'No (N)'	System	14 Sep 2020 02:02:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:25', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'cff7f4d8-1fda-4b13-96c0-9394d08d7d22'	System	14 Sep 2020 02:02:26
User entered '13 Sep 2020 22:02'	System	14 Sep 2020 02:02:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 7'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:00:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ddade0d-d1ca-4229-addb-8e0021844d75'	System	14 Sep 2020 16:03:26
User entered 'Yes (Y)'	System	14 Sep 2020 16:03:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:00:47', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ddade0d-d1ca-4229-addb-8e0021844d75'	System	14 Sep 2020 16:03:26
User entered '98.8'	System	14 Sep 2020 16:03:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:00:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ddade0d-d1ca-4229-addb-8e0021844d75'	System	14 Sep 2020 16:03:26
User entered 'No (N)'	System	14 Sep 2020 16:03:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:00:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6ddade0d-d1ca-4229-addb-8e0021844d75'	System	14 Sep 2020 16:03:26
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:03:26

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:08', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'a04e7874-5130-40e8-b222-a2dd2ab3cffe'	System	08 Sep 2020 15:54:25
User entered 'None (1)'	System	08 Sep 2020 15:54:25

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'a04e7874-5130-40e8-b222-a2dd2ab3cffe'	System	08 Sep 2020 15:54:25
User entered 'No (N)'	System	08 Sep 2020 15:54:25

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'a04e7874-5130-40e8-b222-a2dd2ab3cffe'	System	08 Sep 2020 15:54:25
User entered 'No (N)'	System	08 Sep 2020 15:54:25

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:17', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'a04e7874-5130-40e8-b222-a2dd2ab3cffe'	System	08 Sep 2020 15:54:25
User entered 'None (1)'	System	08 Sep 2020 15:54:25

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'a04e7874-5130-40e8-b222-a2dd2ab3cffe'	System	08 Sep 2020 15:54:25
User entered '08 Sep 2020 11:54'	System	08 Sep 2020 15:54:25

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:02', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9475a264-b38a-4eba-8658-04234d5eef7d'	System	08 Sep 2020 23:04:29
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 23:04:29

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:08', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9475a264-b38a-4eba-8658-04234d5eef7d'	System	08 Sep 2020 23:04:29
User entered 'No (N)'	System	08 Sep 2020 23:04:29

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:17', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9475a264-b38a-4eba-8658-04234d5eef7d'	System	08 Sep 2020 23:04:29
User entered 'No (N)'	System	08 Sep 2020 23:04:29

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9475a264-b38a-4eba-8658-04234d5eef7d'	System	08 Sep 2020 23:04:29
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 23:04:29

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:24', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9475a264-b38a-4eba-8658-04234d5eef7d'	System	08 Sep 2020 23:04:29
User entered '08 Sep 2020 19:04'	System	08 Sep 2020 23:04:29

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 2'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '57158dd0-c8f7-417b-a6d6-f997c7d7f132'	System	09 Sep 2020 16:05:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	09 Sep 2020 16:05:53

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '57158dd0-c8f7-417b-a6d6-f997c7d7f132'	System	09 Sep 2020 16:05:53
User entered 'No (N)'	System	09 Sep 2020 16:05:53

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '57158dd0-c8f7-417b-a6d6-f997c7d7f132'	System	09 Sep 2020 16:05:53
User entered 'No (N)'	System	09 Sep 2020 16:05:53

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:04:59', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '57158dd0-c8f7-417b-a6d6-f997c7d7f132'	System	09 Sep 2020 16:05:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	09 Sep 2020 16:05:53

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:02', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '57158dd0-c8f7-417b-a6d6-f997c7d7f132'	System	09 Sep 2020 16:05:53
User entered '09 Sep 2020 12:05'	System	09 Sep 2020 16:05:53

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 3'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:15', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered 'Yes (Y)'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:26', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered '15'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered 'Yes (Y)'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered '15'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5e02640e-4a56-467f-a916-44b46a148aa3'	System	10 Sep 2020 19:43:51
User entered '10 Sep 2020 15:43'	System	10 Sep 2020 19:43:51

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 4'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ae0425e3-6b4c-4dae-aaab-9a8b23651de8'	System	11 Sep 2020 16:07:52
User entered 'None (1)'	System	11 Sep 2020 16:07:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ae0425e3-6b4c-4dae-aaab-9a8b23651de8'	System	11 Sep 2020 16:07:52
User entered 'No (N)'	System	11 Sep 2020 16:07:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ae0425e3-6b4c-4dae-aaab-9a8b23651de8'	System	11 Sep 2020 16:07:52
User entered 'No (N)'	System	11 Sep 2020 16:07:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:47', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ae0425e3-6b4c-4dae-aaab-9a8b23651de8'	System	11 Sep 2020 16:07:52
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 16:07:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:05:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ae0425e3-6b4c-4dae-aaab-9a8b23651de8'	System	11 Sep 2020 16:07:52
User entered '11 Sep 2020 12:05'	System	11 Sep 2020 16:07:52

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 5'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:21', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd11eef8e-a7ec-4971-bf2d-e40098a36d1f'	System	12 Sep 2020 16:17:50
User entered 'None (1)'	System	12 Sep 2020 16:17:50

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:24', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd11eef8e-a7ec-4971-bf2d-e40098a36d1f'	System	12 Sep 2020 16:17:50
User entered 'No (N)'	System	12 Sep 2020 16:17:50

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:27', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd11eef8e-a7ec-4971-bf2d-e40098a36d1f'	System	12 Sep 2020 16:17:50
User entered 'No (N)'	System	12 Sep 2020 16:17:50

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:29', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd11eef8e-a7ec-4971-bf2d-e40098a36d1f'	System	12 Sep 2020 16:17:50
User entered 'None (1)'	System	12 Sep 2020 16:17:50

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd11eef8e-a7ec-4971-bf2d-e40098a36d1f'	System	12 Sep 2020 16:17:50
User entered '12 Sep 2020 12:16'	System	12 Sep 2020 16:17:50

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 6'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2a074a72-fef6-47c6-ab1e-6695f4993a9f'	System	14 Sep 2020 02:02:54
User entered 'None (1)'	System	14 Sep 2020 02:02:54

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2a074a72-fef6-47c6-ab1e-6695f4993a9f'	System	14 Sep 2020 02:02:54
User entered 'No (N)'	System	14 Sep 2020 02:02:54

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:36', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2a074a72-fef6-47c6-ab1e-6695f4993a9f'	System	14 Sep 2020 02:02:54
User entered 'No (N)'	System	14 Sep 2020 02:02:54

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:49', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2a074a72-fef6-47c6-ab1e-6695f4993a9f'	System	14 Sep 2020 02:02:54
User entered 'None (1)'	System	14 Sep 2020 02:02:54

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:02:52', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2a074a72-fef6-47c6-ab1e-6695f4993a9f' User entered '13 Sep 2020 22:02'	System	14 Sep 2020 02:02:54
	System	14 Sep 2020 02:02:54

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 7'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:04', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '48be9883-4de3-4f8c-a8c5-e6a721d7ef66'	System	14 Sep 2020 16:04:17
User entered 'None (1)'	System	14 Sep 2020 16:04:17

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '48be9883-4de3-4f8c-a8c5-e6a721d7ef66'	System	14 Sep 2020 16:04:17
User entered 'No (N)'	System	14 Sep 2020 16:04:17

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:09', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '48be9883-4de3-4f8c-a8c5-e6a721d7ef66'	System	14 Sep 2020 16:04:17
User entered 'No (N)'	System	14 Sep 2020 16:04:17

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '48be9883-4de3-4f8c-a8c5-e6a721d7ef66'	System	14 Sep 2020 16:04:17
User entered 'None (1)'	System	14 Sep 2020 16:04:17

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '48be9883-4de3-4f8c-a8c5-e6a721d7ef66'	System	14 Sep 2020 16:04:17
User entered '14 Sep 2020 12:01'	System	14 Sep 2020 16:04:17

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:36', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'None (0)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered 'No (N)'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T11:54:47', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'dd348332-71e5-407a-9464-b3e2464144d4'	System	08 Sep 2020 15:54:51
User entered '08 Sep 2020 11:54'	System	08 Sep 2020 15:54:51

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'None (0)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered 'No (N)'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-08T19:04:53', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5d08a567-1ac8-4a92-acb5-450aac7c0fc4'	System	08 Sep 2020 23:04:55
User entered '08 Sep 2020 19:04'	System	08 Sep 2020 23:04:55

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 2'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:37', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'None (0)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered 'No (N)'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-09T12:05:45', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f50c1b5d-eab3-40ed-90eb-f8fe88fb7562'	System	09 Sep 2020 16:06:23
User entered '09 Sep 2020 12:05'	System	09 Sep 2020 16:06:23

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 3'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:43:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'None (0)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:09', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'None (0)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'Some interference with activity not requiring medical attention (2)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered 'No (N)'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-10T15:44:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0daf5064-c355-48dd-9f0a-b2174322872c'	System	10 Sep 2020 19:44:26
User entered '10 Sep 2020 15:44'	System	10 Sep 2020 19:44:26

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 4'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'None (0)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'No interference with activity (1)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:12', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'No interference with activity (1)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'No interference with activity (1)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'None (0)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'None (0)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:27', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered 'No (N)'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-11T12:06:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '9f83af72-f152-40d7-8a1b-f3253ed4f1c2'	System	11 Sep 2020 16:08:12
User entered '11 Sep 2020 12:06'	System	11 Sep 2020 16:08:12

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 5'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:37', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:46', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'None (0)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered 'No (N)'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-12T12:16:54', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'ded882c2-0d18-4403-b9f1-0b90386e1653'	System	12 Sep 2020 16:17:54
User entered '12 Sep 2020 12:16'	System	12 Sep 2020 16:17:54

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 6'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:25', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'None (0)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered 'No (N)'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-13T22:03:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '0dc39363-b75e-4b62-a363-7e36ed138eeb'	System	14 Sep 2020 02:03:45
User entered '13 Sep 2020 22:03'	System	14 Sep 2020 02:03:45

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	08 Sep 2020 15:21:34
User entered 'Day 7'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:26', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:28', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:33', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'None (0)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered 'No (N)'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-09-14T12:01:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2d8031b8-f018-43bc-a941-f4c097c1a3cc'	System	14 Sep 2020 16:05:49
User entered '14 Sep 2020 12:01'	System	14 Sep 2020 16:05:49

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:21:34

US3722158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:34:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:21:34

US3722158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 19:46:56

US3722158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '15 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 19:46:56

US3722158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	15 Sep 2020 19:46:56

US3722158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 19:46:56

US3722158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 19:47:01

US3722158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	15 Sep 2020 19:47:01

US3722158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	22 Sep 2020 20:13:11

US3722158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '22 Sep 2020'	Kayla Peay (b) (4)	22 Sep 2020 20:13:11

US3722158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	22 Sep 2020 20:13:11

US3722158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	22 Sep 2020 20:13:11

US3722158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	22 Sep 2020 20:13:13

US3722158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	22 Sep 2020 20:13:13

US3722158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:31:46

US3722158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '29 Sep 2020'	Kayla Peay (b) (4)	29 Sep 2020 20:31:46

US3722158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	29 Sep 2020 20:31:46

US3722158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Kayla Peay (b) (4)	29 Sep 2020 20:31:46

US3722158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:30:33

US3722158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	29 Sep 2020 20:30:33

US3722158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 14:21:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4)	05 Oct 2020 14:21:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	29 Sep 2020 20:30:57
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:30:57
	(b) (4)	
	Kayla Peay (b) (4)	29 Sep 2020 20:30:41
	(b) (4)	

US3722158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:46:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	21 Oct 2020 15:31:10
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:43:53
User entered '5 Oct 2020' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	05 Oct 2020 14:21:56
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 20:30:57
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	29 Sep 2020 20:30:57
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	29 Sep 2020 20:30:57
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 20:30:41
User entered '29 Sep 2020'	Kayla Peay (b) (4) (b) (4)	29 Sep 2020 20:30:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	05 Oct 2020 14:22:08
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	Amy Ford (b) (4)	05 Oct 2020 14:22:08
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Clinic (Clinic)'	System	05 Oct 2020 14:21:56
	Kayla Peay (b) (4)	29 Sep 2020 20:30:57
	(b) (4)	
	Kayla Peay (b) (4)	29 Sep 2020 20:30:41
	(b) (4)	

US3722158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'VISIT3'	System	05 Oct 2020 14:21:56
User entered empty.	System	29 Sep 2020 20:30:57
User entered 'VISIT3'	System	29 Sep 2020 20:30:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '5 Oct 2020'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '10:13'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '5 Oct 2020 10:13'	System	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '97.8' F	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered empty.	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '85'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'bpm'	System	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '18'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'breaths/min'	System	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '113'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '64'	Marlee Smith (b) (4)	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'mmHg'	System	21 Oct 2020 15:31:41

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57

US3722158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57

US3722158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Marlee Smith (b) (4)	21 Oct 2020 15:31:45

US3722158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '5 Oct 2020'	Marlee Smith (b) (4)	21 Oct 2020 15:31:45

US3722158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Marlee Smith (b) (4)	21 Oct 2020 15:31:55

US3722158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '5 Oct 2020'	Marlee Smith (b) (4)	21 Oct 2020 15:31:55

US3722158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered '10:26'	Marlee Smith (b) (4)	21 Oct 2020 15:31:55

US3722158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered '5 Oct 2020 10:26'	System	21 Oct 2020 15:31:55

US3722158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:07:15
User entered 'Yes (Y)'	Marlee Smith (b) (4)	21 Oct 2020 15:31:57

US3722158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	21 Oct 2020 15:31:57

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 64'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-07T10:57:50', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe50c690-1d72-45c6-9fbc-2d056d1289a1'	System	07 Oct 2020 14:58:18
User entered 'No (N)'	System	07 Oct 2020 14:58:18

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-07T10:58:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe50c690-1d72-45c6-9fbc-2d056d1289a1'	System	07 Oct 2020 14:58:18
User entered 'No (N)'	System	07 Oct 2020 14:58:18

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-07T10:58:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'fe50c690-1d72-45c6-9fbc-2d056d1289a1' User entered '07 Oct 2020 10:58:13'	System	07 Oct 2020 14:58:18
	System	07 Oct 2020 14:58:18

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 71'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-14T02:17:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '61ce5b22-83e0-441a-89ab-6a09083709b6'	System	14 Oct 2020 06:17:31
User entered 'No (N)'	System	14 Oct 2020 06:17:31

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-14T02:17:24', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '61ce5b22-83e0-441a-89ab-6a09083709b6'	System	14 Oct 2020 06:17:31
User entered 'No (N)'	System	14 Oct 2020 06:17:31

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-14T02:17:31', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '61ce5b22-83e0-441a-89ab-6a09083709b6' User entered '14 Oct 2020 02:17:31'	System	14 Oct 2020 06:17:31
	System	14 Oct 2020 06:17:31

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 78'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-21T14:40:53', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'df139b2b-c02e-49e1-b1fe-7e89eec61b47'	System	21 Oct 2020 18:41:03
User entered 'No (N)'	System	21 Oct 2020 18:41:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-21T14:40:57', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'df139b2b-c02e-49e1-b1fe-7e89eec61b47'	System	21 Oct 2020 18:41:03
User entered 'No (N)'	System	21 Oct 2020 18:41:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-10-21T14:41:01', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'df139b2b-c02e-49e1-b1fe-7e89eec61b47'	System	21 Oct 2020 18:41:03
User entered '21 Oct 2020 14:41:01'	System	21 Oct 2020 18:41:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 92'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:15:47
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 99'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-12T13:23:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd7ad1eb9-10d5-4ab6-82b7-6f77d2e2b47c'	System	12 Nov 2020 18:23:52
User entered 'No (N)'	System	12 Nov 2020 18:23:52

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-12T13:23:36', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd7ad1eb9-10d5-4ab6-82b7-6f77d2e2b47c'	System	12 Nov 2020 18:23:52
User entered 'No (N)'	System	12 Nov 2020 18:23:52

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-12T13:23:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd7ad1eb9-10d5-4ab6-82b7-6f77d2e2b47c'	System	12 Nov 2020 18:23:52
User entered '12 Nov 2020 13:23:48'	System	12 Nov 2020 18:23:52

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered 'Day 106'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-18T12:38:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '28c1007a-d5db-45ef-982a-ef0ca025d896'	System	18 Nov 2020 17:38:26
User entered 'No (N)'	System	18 Nov 2020 17:38:26

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-18T12:38:17', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '28c1007a-d5db-45ef-982a-ef0ca025d896'	System	18 Nov 2020 17:38:26
User entered 'No (N)'	System	18 Nov 2020 17:38:26

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-18T12:38:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '28c1007a-d5db-45ef-982a-ef0ca025d896'	System	18 Nov 2020 17:38:26
User entered '18 Nov 2020 12:38:20'	System	18 Nov 2020 17:38:26

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 20:59:03

US3722158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:50:37
Data entry locked.	System	07 Aug 2020 20:59:03
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 20:59:03

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-11-24T08:27:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2b8a7da3-7f7b-4e92-8a77-fdd863de5446'	System	24 Nov 2020 13:27:34
User entered 'No (N)'	System	24 Nov 2020 13:27:34

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-11-24T08:27:26', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2b8a7da3-7f7b-4e92-8a77-fdd863de5446'	System	24 Nov 2020 13:27:34
User entered 'No (N)'	System	24 Nov 2020 13:27:34

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-24T08:27:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '2b8a7da3-7f7b-4e92-8a77-fdd863de5446'	System	24 Nov 2020 13:27:34
User entered '24 Nov 2020 08:27:30'	System	24 Nov 2020 13:27:34

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-11-29T02:49:30', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7948c342-cd0e-4e17-b9b6-2d91423bcb1f' User entered 'No (N)'	System	29 Nov 2020 07:49:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-11-29T02:49:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7948c342-cd0e-4e17-b9b6-2d91423bcb1f' User entered 'No (N)'	System	29 Nov 2020 07:49:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-11-29T02:49:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '7948c342-cd0e-4e17-b9b6-2d91423bcb1f' User entered '29 Nov 2020 02:49:38'	System	29 Nov 2020 07:49:38
	System	29 Nov 2020 07:49:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-12-10T09:27:35', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f576f66d-eec5-4bd7-81a4-bb693fcb1d1c'	System	10 Dec 2020 14:27:47
User entered 'No (N)'	System	10 Dec 2020 14:27:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-12-10T09:27:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f576f66d-eec5-4bd7-81a4-bb693fcb1d1c'	System	10 Dec 2020 14:27:47
User entered 'No (N)'	System	10 Dec 2020 14:27:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-12-10T09:27:43', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f576f66d-eec5-4bd7-81a4-bb693fcb1d1c' User entered '10 Dec 2020 09:27:43'	System	10 Dec 2020 14:27:47
	System	10 Dec 2020 14:27:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-12-14T10:04:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd4016920-75cc-4811-b402-2e34318e803a'	System	14 Dec 2020 15:04:59
User entered 'No (N)'	System	14 Dec 2020 15:04:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-12-14T10:04:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd4016920-75cc-4811-b402-2e34318e803a'	System	14 Dec 2020 15:04:59
User entered 'No (N)'	System	14 Dec 2020 15:04:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-12-14T10:04:58', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'd4016920-75cc-4811-b402-2e34318e803a'	System	14 Dec 2020 15:04:59
User entered '14 Dec 2020 10:04:58'	System	14 Dec 2020 15:04:59

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-12-21T08:42:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5a5559ec-c1ba-4723-b68c-a173a85df9a5'	System	21 Dec 2020 13:42:54
User entered 'No (N)'	System	21 Dec 2020 13:42:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-12-21T08:42:49', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5a5559ec-c1ba-4723-b68c-a173a85df9a5'	System	21 Dec 2020 13:42:54
User entered 'No (N)'	System	21 Dec 2020 13:42:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-12-21T08:42:53', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5a5559ec-c1ba-4723-b68c-a173a85df9a5'	System	21 Dec 2020 13:42:54
User entered '21 Dec 2020 08:42:53'	System	21 Dec 2020 13:42:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2020-12-29T11:12:37', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3beb4480-d60f-4b1a-bd74-af7ba913f6b2'	System	29 Dec 2020 16:12:50
User entered 'No (N)'	System	29 Dec 2020 16:12:50

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2020-12-29T11:12:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3beb4480-d60f-4b1a-bd74-af7ba913f6b2'	System	29 Dec 2020 16:12:50
User entered 'No (N)'	System	29 Dec 2020 16:12:50

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2020-12-29T11:12:45', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3beb4480-d60f-4b1a-bd74-af7ba913f6b2' User entered '29 Dec 2020 11:12:45'	System	29 Dec 2020 16:12:50
	System	29 Dec 2020 16:12:50

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2021-01-03T08:36:24', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b069af77-0808-4f30-99a8-68b9d9459a6d'	System	03 Jan 2021 13:36:30
User entered 'No (N)'	System	03 Jan 2021 13:36:30

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2021-01-03T08:36:29', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b069af77-0808-4f30-99a8-68b9d9459a6d'	System	03 Jan 2021 13:36:30
User entered 'No (N)'	System	03 Jan 2021 13:36:30

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2021-01-03T08:36:32', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'b069af77-0808-4f30-99a8-68b9d9459a6d'	System	03 Jan 2021 13:36:30
User entered '03 Jan 2021 08:36:32'	System	03 Jan 2021 13:36:30

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2021-01-11T18:50:36', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f97a202d-3a57-4261-95b5-69ebcd3715a9'	System	11 Jan 2021 23:50:47
User entered 'No (N)'	System	11 Jan 2021 23:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2021-01-11T18:50:41', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f97a202d-3a57-4261-95b5-69ebcd3715a9'	System	11 Jan 2021 23:50:47
User entered 'No (N)'	System	11 Jan 2021 23:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2021-01-11T18:50:44', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'f97a202d-3a57-4261-95b5-69ebcd3715a9' User entered '11 Jan 2021 18:50:44'	System	11 Jan 2021 23:50:47
	System	11 Jan 2021 23:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (e723b071170649f4)', Time: '2021-01-17T11:12:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '662ac641-2713-4e15-98de-4a79d4f70761'	System	17 Jan 2021 16:12:13
User entered 'No (N)'	System	17 Jan 2021 16:12:13

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Have you been exposed to someone with 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 (e723b071170649f4)', Time: '2021-01-17T11:12:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '662ac641-2713-4e15-98de-4a79d4f70761'	System	17 Jan 2021 16:12:13
User entered 'No (N)'	System	17 Jan 2021 16:12:13

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e723b071170649f4)', Time: '2021-01-17T11:12:11', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '662ac641-2713-4e15-98de-4a79d4f70761' User entered '17 Jan 2021 11:12:11'	System	17 Jan 2021 16:12:13
	System	17 Jan 2021 16:12:13

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-01-26T15:21:14', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '59a0b981-09d7-4d1a-989d-0084c80500e6'	System	26 Jan 2021 21:11:29
User entered 'No (N)'	System	26 Jan 2021 21:11:29

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-01-26T15:21:22', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '59a0b981-09d7-4d1a-989d-0084c80500e6'	System	26 Jan 2021 21:11:29
User entered 'No (N)'	System	26 Jan 2021 21:11:29

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-01-26T15:21:25', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '59a0b981-09d7-4d1a-989d-0084c80500e6'	System	26 Jan 2021 21:11:29
User entered '26 Jan 2021 15:21:25'	System	26 Jan 2021 21:11:29

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-01-31T08:50:39', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '70a52647-3cb5-4b04-bb3c-cf76c6f60660'	System	31 Jan 2021 13:50:47
User entered 'No (N)'	System	31 Jan 2021 13:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-01-31T08:50:48', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '70a52647-3cb5-4b04-bb3c-cf76c6f60660'	System	31 Jan 2021 13:50:47
User entered 'No (N)'	System	31 Jan 2021 13:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-01-31T08:50:51', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '70a52647-3cb5-4b04-bb3c-cf76c6f60660'	System	31 Jan 2021 13:50:47
User entered '31 Jan 2021 08:50:51'	System	31 Jan 2021 13:50:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-08T09:24:02', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered 'Yes (Y)'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-02-08T09:24:07', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered 'No (N)'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-08T09:24:13', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered 'No (N)'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-08T09:24:18', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered 'Yes (Y)'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Please 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 (31842ab3268a6412)', Time: '2021-02-08T09:24:23', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-08T09:24:27', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'eaf30fdf-afb8-49a5-8732-8e8902e58c4d'	System	08 Feb 2021 14:24:35
User entered '08 Feb 2021 09:24:27'	System	08 Feb 2021 14:24:35

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-15T13:44:55', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '23f528c2-2dc5-4df6-b51c-c3b9ed27d380'	System	15 Feb 2021 18:45:05
User entered 'No (N)'	System	15 Feb 2021 18:45:05

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-02-15T13:45:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '23f528c2-2dc5-4df6-b51c-c3b9ed27d380'	System	15 Feb 2021 18:45:05
User entered 'No (N)'	System	15 Feb 2021 18:45:05

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-15T13:45:03', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '23f528c2-2dc5-4df6-b51c-c3b9ed27d380'	System	15 Feb 2021 18:45:05
User entered '15 Feb 2021 13:45:03'	System	15 Feb 2021 18:45:05

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-22T10:33:34', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e4dfa02f-ef7a-42a7-a8f0-c7fbd97c71e2'	System	22 Feb 2021 15:33:45
User entered 'No (N)'	System	22 Feb 2021 15:33:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-02-22T10:33:38', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e4dfa02f-ef7a-42a7-a8f0-c7fbd97c71e2'	System	22 Feb 2021 15:33:45
User entered 'No (N)'	System	22 Feb 2021 15:33:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-22T10:33:40', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e4dfa02f-ef7a-42a7-a8f0-c7fbd97c71e2'	System	22 Feb 2021 15:33:45
User entered '22 Feb 2021 10:33:40'	System	22 Feb 2021 15:33:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-28T08:30:42', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered 'Yes (Y)'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-02-28T08:30:47', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered 'No (N)'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-28T08:30:52', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered 'No (N)'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-02-28T08:30:58', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered 'Yes (Y)'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Please 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 (31842ab3268a6412)', Time: '2021-02-28T08:31:02', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-28T08:31:05', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3f5035b1-f1bf-4611-8b35-028ad289ad73'	System	28 Feb 2021 13:31:16
User entered '28 Feb 2021 08:31:05'	System	28 Feb 2021 13:31:16

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-08T09:16:04-05:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5527c188-1960-4098-a0d4-9c0d70d867a0'	System	08 Mar 2021 14:16:18
User entered 'No (N)'	System	08 Mar 2021 14:16:18

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-03-08T09:16:09-05:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5527c188-1960-4098-a0d4-9c0d70d867a0'	System	08 Mar 2021 14:16:18
User entered 'No (N)'	System	08 Mar 2021 14:16:18

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-08T09:16:14-05:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5527c188-1960-4098-a0d4-9c0d70d867a0'	System	08 Mar 2021 14:16:18
User entered '08 Mar 2021 09:16:14'	System	08 Mar 2021 14:16:18

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-15T11:48:50-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '10d9e140-8a85-4559-8935-c83a798a9b00'	System	15 Mar 2021 15:49:28
User entered 'No (N)'	System	15 Mar 2021 15:49:28

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-03-15T11:49:00-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '10d9e140-8a85-4559-8935-c83a798a9b00'	System	15 Mar 2021 15:49:28
User entered 'No (N)'	System	15 Mar 2021 15:49:28

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-15T11:49:22-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '10d9e140-8a85-4559-8935-c83a798a9b00'	System	15 Mar 2021 15:49:28
User entered '15 Mar 2021 11:49:22'	System	15 Mar 2021 15:49:28

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-22T10:27:32-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '80c4b8fd-df71-4199-ae97-5b4624f3c9db'	System	22 Mar 2021 14:27:54
User entered 'No (N)'	System	22 Mar 2021 14:27:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-03-22T10:27:42-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '80c4b8fd-df71-4199-ae97-5b4624f3c9db'	System	22 Mar 2021 14:27:54
User entered 'No (N)'	System	22 Mar 2021 14:27:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-22T10:27:47-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '80c4b8fd-df71-4199-ae97-5b4624f3c9db' User entered '22 Mar 2021 10:27:47'	System	22 Mar 2021 14:27:54
	System	22 Mar 2021 14:27:54

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-29T07:58:21-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0'	System	29 Mar 2021 11:59:47
User entered 'Yes (Y)'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-03-29T07:58:27-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0'	System	29 Mar 2021 11:59:47
User entered 'No (N)'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-29T07:58:34-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered 'Yes (Y)'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '1'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '1'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '1'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '1'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '1'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:11-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '0'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Please 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 (31842ab3268a6412)', Time: '2021-03-29T07:59:22-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0'	System	29 Mar 2021 11:59:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-03-29T07:59:28-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0'	System	29 Mar 2021 11:59:47
User entered 'No (N)'	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-03-29T07:59:36-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'c9d20a40-e8cb-45e0-a454-40a2ed7ff3f0' User entered '29 Mar 2021 07:59:36'	System	29 Mar 2021 11:59:47
	System	29 Mar 2021 11:59:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-05T13:22:40-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered 'Yes (Y)'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-04-05T13:22:45-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered 'No (N)'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-05T13:22:54-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered 'Yes (Y)'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '0'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '1'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '1'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '0'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '1'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '1'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7' User entered '0'	System	05 Apr 2021 17:23:45
	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:18-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '1'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Please 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 (31842ab3268a6412)', Time: '2021-04-05T13:23:22-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-05T13:23:28-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered 'No (N)'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-05T13:23:32-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '3c988864-110c-42a4-b71f-61b72a8055c7'	System	05 Apr 2021 17:23:45
User entered '05 Apr 2021 13:23:32'	System	05 Apr 2021 17:23:45

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-12T09:59:39-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6aa0606f-2fb9-490a-8fc4-39d071fc9823'	System	12 Apr 2021 13:59:53
User entered 'No (N)'	System	12 Apr 2021 13:59:53

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-04-12T09:59:43-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6aa0606f-2fb9-490a-8fc4-39d071fc9823'	System	12 Apr 2021 13:59:53
User entered 'No (N)'	System	12 Apr 2021 13:59:53

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-12T09:59:46-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '6aa0606f-2fb9-490a-8fc4-39d071fc9823'	System	12 Apr 2021 13:59:53
User entered '12 Apr 2021 09:59:46'	System	12 Apr 2021 13:59:53

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-20T08:55:28-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '1f2b2689-08b0-49d7-8833-6a6c2f806990'	System	20 Apr 2021 12:55:38
User entered 'No (N)'	System	20 Apr 2021 12:55:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-04-20T08:55:31-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '1f2b2689-08b0-49d7-8833-6a6c2f806990'	System	20 Apr 2021 12:55:38
User entered 'No (N)'	System	20 Apr 2021 12:55:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-20T08:55:34-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '1f2b2689-08b0-49d7-8833-6a6c2f806990' User entered '20 Apr 2021 08:55:34'	System	20 Apr 2021 12:55:38
	System	20 Apr 2021 12:55:38

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-04-26T08:43:12-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '66d309f9-11b2-47fd-b62e-b4a6b746eeda' User entered 'No (N)'	System	26 Apr 2021 12:43:27
	System	26 Apr 2021 12:43:27

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-04-26T08:43:17-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '66d309f9-11b2-47fd-b62e-b4a6b746eeda' User entered 'No (N)'	System	26 Apr 2021 12:43:27

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-04-26T08:43:24-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '66d309f9-11b2-47fd-b62e-b4a6b746eeda' User entered '26 Apr 2021 08:43:24'	System	26 Apr 2021 12:43:27
	System	26 Apr 2021 12:43:27

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[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 (31842ab3268a6412)', Time: '2021-05-03T08:39:42-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5c70d433-88af-49a3-95de-89f71fcc9dfc'	System	03 May 2021 12:40:06
User entered 'No (N)'	System	03 May 2021 12:40:06

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

Have you been exposed to someone with 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 (31842ab3268a6412)', Time: '2021-05-03T08:39:54-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5c70d433-88af-49a3-95de-89f71fcc9dfc'	System	03 May 2021 12:40:06
User entered 'No (N)'	System	03 May 2021 12:40:06

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-05-03T08:40:00-04:00', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: '5c70d433-88af-49a3-95de-89f71fcc9dfc'	System	03 May 2021 12:40:06
User entered '03 May 2021 08:40:00'	System	03 May 2021 12:40:06

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:15:47

US3722158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:15:47
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:15:47

US3722158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:34:43

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)	24 Apr 2021 03:33:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-28T08:31:16', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e896d416-efd7-48d8-b064-c06a9d8fe104'	System	28 Feb 2021 13:31:21
User entered 'No (N)'	System	28 Feb 2021 13:31:21

US3722158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:34:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:33:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31842ab3268a6412)', Time: '2021-02-28T08:31:20', User OID: 'PatientReportedOutcome (US3722158)', ODM File OID: 'e896d416-efd7-48d8-b064-c06a9d8fe104'	System	28 Feb 2021 13:31:21
User entered '28 Feb 2021 08:31:20'	System	28 Feb 2021 13:31:21

US3722158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:20:19
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Nov 2020 20:44:42

US3722158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:20:19
User entered '02 Nov 2020'	Taylor Wilson (b) (4)	02 Nov 2020 20:44:42

US3722158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:20:19
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	02 Nov 2020 20:44:42

US3722158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:20:19
User entered empty.	Taylor Wilson (b) (4)	02 Nov 2020 20:44:42

US3722158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:20:19
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Nov 2020 20:44:46

US3722158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:28:57
User entered 'I'	System	02 Nov 2020 20:44:46

US3722158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Dec 2020 19:31:42

US3722158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '4 Dec 2020'	Marlee Smith (b) (4)	10 Dec 2020 19:31:42

US3722158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	10 Dec 2020 19:31:42

US3722158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Marlee Smith (b) (4)	10 Dec 2020 19:31:42

US3722158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Dec 2020 19:31:46

US3722158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:37
User entered 'I'	System	10 Dec 2020 19:31:46

US3722158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Jan 2021 19:26:41

US3722158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '04 Jan 2021'	Taylor Wilson (b) (4)	04 Jan 2021 19:26:41

US3722158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	04 Jan 2021 19:26:41

US3722158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Taylor Wilson (b) (4)	04 Jan 2021 19:26:41

US3722158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Jan 2021 19:26:48

US3722158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:17
User entered 'I'	System	04 Jan 2021 19:26:48

US3722158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Feb 2021 20:13:28

US3722158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '02 Feb 2021'	Taylor Wilson (b) (4)	02 Feb 2021 20:13:28

US3722158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	02 Feb 2021 20:13:28

US3722158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Taylor Wilson (b) (4)	02 Feb 2021 20:13:28

US3722158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Feb 2021 20:13:33

US3722158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:44
User entered 'I'	System	02 Feb 2021 20:13:33

US3722158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:55
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Feb 2021 19:15:46

US3722158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:55
User entered '22 Feb 2021'	(b) (4) Marlee Smith (b) (4)	22 Feb 2021 19:15:46

US3722158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:55
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	22 Feb 2021 19:15:46

US3722158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'VISIT4'	System	22 Feb 2021 19:15:46

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Yes (Y)'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '22 Feb 2021'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '14:18'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '22 Feb 2021 14:18'	System	30 Mar 2021 15:28:24

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '98' F	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered empty.	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '89'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'bpm'	System	30 Mar 2021 15:28:24

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '17'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'breaths/min'	System	30 Mar 2021 15:28:24

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '131'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'mmHg'	System	30 Mar 2021 15:28:24

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:55
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '80'	Marlee Smith (b) (4)	30 Mar 2021 15:28:24
	(b) (4)	

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'mmHg'	System	30 Mar 2021 15:28:24

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49

US3722158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:43:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49

US3722158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:55
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	22 Feb 2021 19:15:51

US3722158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:55
User entered empty.	Marlee Smith (b) (4)	22 Feb 2021 19:15:51

US3722158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 20:50:06

US3722158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '22 Feb 2021'	Marlee Smith (b) (4)	02 Mar 2021 20:50:06

US3722158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered '14:37'	Marlee Smith (b) (4)	02 Mar 2021 20:50:06

US3722158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered '22 Feb 2021 14:37'	System	02 Mar 2021 20:50:06

US3722158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:21:51
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Feb 2021 19:15:55

US3722158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:00:49
User entered 'I'	System	22 Feb 2021 19:15:55

US3722158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	06 Apr 2021 19:22:33
	(b) (4)	

US3722158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '06 Apr 2021'	Taylor Wilson (b) (4)	06 Apr 2021 19:22:33
	(b) (4)	

US3722158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	06 Apr 2021 19:22:33
	(b) (4)	

US3722158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	06 Apr 2021 19:22:33
	(b) (4)	

US3722158

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	06 Apr 2021 19:22:37
	(b) (4)	

US3722158

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 19:22:37

US3722158

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

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 21:38:53

US3722158

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

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '18 Jan 2021'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 21:38:53
	(b) (4)	

US3722158

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

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[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 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Clinic (Clinic)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:38:53

US3722158

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

Form: Visit Date

Generated On: 10 Jun 2021 09:34:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 21:38:53

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '18 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[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 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '0'	(b) (4) Marlee Smith (b) (4)	22 Apr 2021 12:46:52
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:56:28

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:31:32
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:46:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:46:52
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:19:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:56:28

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '18 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:43:20
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	18 Jan 2021 21:39:04
	(b) (4)	

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:43:20
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	18 Jan 2021 21:39:04
	(b) (4)	

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User entered empty.	System	18 Jan 2021 21:39:04

US3722158

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

Form: Unblinding

Generated On: 10 Jun 2021 09:34:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User entered empty.	System	18 Jan 2021 21:39:04

US3722158

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 21:39:11
	(b) (4)	

US3722158

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '18 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:11

US3722158

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '16:17'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:11

US3722158

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User entered '18 Jan 2021 16:17'	System	18 Jan 2021 21:39:11

US3722158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:34:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 21:39:19

US3722158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '18 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:19

US3722158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:34:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '16:19'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 21:39:19

US3722158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:34:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:38
User entered '18 Jan 2021 16:19'	System	18 Jan 2021 21:39:19

US3722158

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:34:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:24:48
User closed query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:39:17
Query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no AE to report' (Site from DM).	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:05:56
User opened query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:57:05
User entered 'Yes (Y)' reason for change: New Information	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:11:22
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	17 Feb 2021 20:17:19
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	14 Aug 2020 19:50:40

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:20:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:11:18
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:11:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:10:55
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:10:52
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:26
User entered 'USA-US083-2021-mRNA-1273-P301000012'	System	01 Mar 2021 20:03:05
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 20:03:05
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 19:31:04

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Perirectal abscess, LLT: Perirectal abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:18:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:18:36
Data point term sent to Coder	System	07 Apr 2021 17:18:01
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
User entered 'Perirectal Abscess' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
User closed query 'For coding purposes, please split ABSCESS RELATED TO ANAL FISTULA into separate entries. 1. ABSCESS [RELATED TO ANAL FISTULA] and 2. ANAL FISTULA' (Site from Coder).	(b) (4), (b) (6)	13 Mar 2021 15:46:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Anal abscess, LLT: Anal abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:38:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:38:54
Query 'For coding purposes, please split ABSCESS RELATED TO ANAL FISTULA into separate entries. 1. ABSCESS [RELATED TO ANAL FISTULA] and 2. ANAL FISTULA' answered with 'Updated per query' (Site from Coder).	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:57
Data point term sent to Coder	System	01 Mar 2021 18:40:46
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User entered 'ABSCESS (RELATED TO ANAL FISTULA)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Anal fistula, LLT: Anal fistula - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:42:22

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Feb 2021 11:42:22
User opened query 'For coding purposes, please split ABSCESS RELATED TO ANAL FISTULA into separate entries. 1. ABSCESS [RELATED TO ANAL FISTULA] and 2. ANAL FISTULA' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 11:41:47
Data point term sent to Coder	System	26 Feb 2021 21:16:39
User entered 'Abscess Related to Anal Fistula'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '25 Feb 2021'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '5 Mar 2021' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:32:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Another surgery will be needed in order for this to be ended. This surgery is scheduled for 6 weeks from now and will be entered once this surgery is completed.' (Site from Safety).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 15:45:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:04:38
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:40:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:40:25
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 21:16:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Mar 2021 18:40:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Mar 2021 18:40:25
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Feb 2021 21:16:28
User entered 'I'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '25 Feb 2021'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:32:12
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records have been sent for and records sent. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 15:46:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:06:54
User entered '28 Feb 2021' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:30:54
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated Per PI interpretation on source' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:41:19
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:40:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:40:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 00:59:41
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 21:16:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:30:56
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated Per PI interpretation on source' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:41:25
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:40:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:40:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 00:59:50
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 21:16:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:32:15
Query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.' answered with 'Updated as asked.' (Site from Safety).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 15:51:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Mar 2021 15:51:25
User opened query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:05:32
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:40:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:40:25
User entered 'None (NONE)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 18:40:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 21:16:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	(b) (4), (b) (6)	08 Apr 2021 19:08:04
' (Site from DM). Query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:47
' answered with 'UPdated per records. ' (Site from DM). User opened query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	(b) (4), (b) (6)	23 Mar 2021 17:48:29
' (Site from DM). User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Awaiting medical records' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User entered 'I'	(b) (4), (b) (6) Marlee Smith (b) (4) (b) (4) (b) (4), (b) (6) Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:48:29 17 Mar 2021 19:08:35 17 Mar 2021 14:13:12 26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	(b) (4), (b) (6)	08 Apr 2021 19:07:31
' (Site from DM). Query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:55
' answered with 'Updated per records. ' (Site from DM). User opened query 'Per CDM: Response noted. When Medical Records are received please update accordingly. Thank you.	(b) (4), (b) (6)	23 Mar 2021 17:48:39
' (Site from DM). User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:48:39
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'awaiting medical records' (Site from DM).	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 19:08:47
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:13:21
User entered 'I'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:34:00
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated per records. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:18:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:04:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	26 Feb 2021 21:16:28

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed 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.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:31:47
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.' answered with 'No results are available ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	14 Apr 2021 18:02:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:34:56
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:34:15

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED TO SITE ON 26 FEB 2021 THAT SHE WENT TO THE ER WITH PAIN AND UNDERWENT REMOVAL OF AN ABSCESS CAUSED BY AN ANAL FISTULA ON 25 FEB 2021. SUBJECT EXPECTS TO BE DISCHARGED ON 27 FEB 2021. SITE WILL UPDATE ONCE MEDICAL RECORDS ARE RECEIVED. SUBJECT INDICATED ON 01 MAR 2021 THAT SHE WAS DISCHARGED ON 28 FEB 2021. RECORDS RECEIVED AND REVEIWED BY SITE. MEDICATIONS AND PROCEDURES UPDATED. SUBJECT WAS DISCHARGED ON 2-28-2021 AFTER HAVING AN INCISION AND DRAINAGE OF THE ABSCESS, LITHOTOMY, AND PLACEMENT OF SETON. SUBJECT HAD A CT DONE WHERE THE ABSCESS WAS IDENTIFIED AND LABS WERE DRAWN. WBC WAS 22.1 ON 2-25-2021. NO REFERENCE RANGES PROVIDED IN RECORDS. NO COVID TESTING NOTED IN RECORDS. Title of SAE changed to reflect medical records.' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:23:58
User entered 'SUBJECT REPORTED TO SITE ON 26 FEB 2021 THAT SHE WENT TO THE ER WITH PAIN AND UNDERWENT REMOVAL OF AN ABSCESS CAUSED BY AN ANAL FISTULA ON 25 FEB 2021. SUBJECT EXPECTS TO BE DISCHARGED ON 27 FEB 2021. SITE WILL UPDATE ONCE MEDICAL RECORDS ARE RECEIVED. SUBJECT INDICATED ON 01 MAR 2021 THAT SHE WAS DISCHARGED ON 28 FEB 2021. Records received and reveiwed by site. Medications and procedures updated. Subject was discharged on 2-28-2021 after having an incision and drainage of the abscess, lithotomy, and placement of seton. Subject had a CT done where the abscess was identified and labs were drawn. WBC was 22.1 on 2-25-2021. No reference ranges provided in records. NO COVID TESTING NOTED IN RECORDS.' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:22:12

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EAB) (1725)

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US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UPdated. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:19:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No COVID testing noted in records. Narrative updated. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:18:25
User entered 'SUBJECT REPORTED TO SITE ON 26 FEB 2021 THAT SHE WENT TO THE ER WITH PAIN AND UNDERWENT REMOVAL OF AN ABSCESS CAUSED BY AN ANAL FISTULA ON 25 FEB 2021. SUBJECT EXPECTS TO BE DISCHARGED ON 27 FEB 2021. SITE WILL UPDATE ONCE MEDICAL RECORDS ARE RECEIVED. SUBJECT INDICATED ON 01 MAR 2021 THAT SHE WAS DISCHARGED ON 28 FEB 2021.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:17:30
No COVID testing noted in records.' reason for change: Data Entry Error		
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) (b) (4)	05 Mar 2021 14:04:22

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Narrative](#)

Audit	User	Time (GMT)
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.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:04:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:04:01
User entered 'SUBJECT REPORTED TO SITE ON 26 FEB 2021 THAT SHE WENT TO THE ER WITH PAIN AND UNDERWENT REMOVAL OF AN ABSCESS CAUSED BY AN ANAL FISTULA ON 25 FEB 2021. SUBJECT EXPECTS TO BE DISCHARGED ON 27 FEB 2021. SITE WILL UPDATE ONCE MEDICAL RECORDS ARE RECEIVED. Subject indicated on 01 MAR 2021 that she was discharged on 28 FEB 2021.' reason for change: Data Entry Error	Kayla Peay (b) (4)	01 Mar 2021 18:40:25
User entered 'Subject reported to site on 26 FEB 2021 that she went to the ER with pain and underwent removal of an abscess caused by an anal fistula on 25 FEB 2021. Subject expects to be discharged on 27 FEB 2021. Site will update once medical records are received.'	Kayla Peay (b) (4)	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:34:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 21:16:28

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:10:43
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:07:37
User entered empty; reason for change New Information	(b) (4), (b) (6)	09 Apr 2021 13:07:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:26
User entered 'USA-US083-2021-mRNA-1273-P301000012'	(b) (4), (b) (6)	02 Mar 2021 14:14:01

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Per DM CLR: Please review AE #s 7 and 8 and verify if these events can be combined with a unifying diagnosis (e.g. Anal Fistula Abscess/Infection). Please review and update as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review AE #s 7 and 8 and verify if these events can be combined with a unifying diagnosis (e.g. Anal Fistula Abscess/Infection). Please review and update as applicable. Otherwise, clarify.' answered with 'Site was initially instructed by safety team to split these terms. However, upon receiving records, this AE will not be serious.' (Site from DM).	(b) (4), (b) (6) Kayla Peay (b) (4) (b) (4)	14 Apr 2021 06:38:19 07 Apr 2021 17:26:27
User opened query 'Per DM CLR: Please review AE #s 7 and 8 and verify if these events can be combined with a unifying diagnosis (e.g. Anal Fistula Abscess/Infection). Please review and update as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:14:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Anal fistula, LLT: Anal fistula - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:06:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:06:57
Data point term sent to Coder	System	01 Mar 2021 20:06:02
User entered 'Anal Fistula'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '01 Feb 2021' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered '25 Feb 2021'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Peay (b) (4)	07 Apr 2021 17:28:50
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Peay (b) (4)	01 Mar 2021 20:05:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0' reason for change: Data Entry Error	Kayla Peay (b) (4)	07 Apr 2021 17:28:50
User entered '1'	(b) (4) Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered '25 Feb 2021'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered '28 Feb 2021'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:51:37
Query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.'	Marlee Smith (b) (4)	15 Mar 2021 14:08:40
answered with 'updated' (Site from Safety).	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4)	15 Mar 2021 14:08:35
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 08Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:38:20
User entered 'None (NONE)'	Kayla Peay (b) (4)	01 Mar 2021 20:05:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User closed query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 06:38:23
Query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' answered with 'will update when medical records are received' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 15:07:41
User opened query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:49:45
User entered 'I'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered '0'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered empty.	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:20:45
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL ON 25 FEB 2021 FOR AN ABSCESS RELATED TO AN ANAL FISTULA. SUBJECT REPORTS SHE WAS DISCHARGED ON 28 FEB 2021. SITE IS PENDING MEDICAL RECORDS. Upon receiving medical records, this event is no longer considered serious.' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 17:28:50
User entered 'Subject was admitted to hospital on 25 FEB 2021 for an abscess related to an anal fistula. Subject reports she was discharged on 28 FEB 2021. Site is pending medical records.'	Kayla Peay (b) (4) (b) (4)	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 17:28:50
User entered '1'	System	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 20:05:04

US3722158

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:34:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 20:05:04

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:08
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 13:05:34
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject already takes Tylenol for headaches and this is listed as ongoing. This is the same medication subject used for the pain at injection site.' (Site from DM).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 15:56:46
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness Day 3, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:09:20

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:34:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 15:06:04
User entered 'No (N)'	Kayla Peay (b) (4)	07 Aug 2020 20:57:36

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
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.	(b) (4) Coder Import (b) (4)	13 Aug 2020 00:01:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 00:01:16
Data point term sent to Coder Coding entries removed.	System Kayla Peay (b) (4)	13 Aug 2020 00:00:52 13 Aug 2020 00:00:28
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)	12 Aug 2020 15:08:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 15:08:11
Data point term sent to Coder User entered 'flonase'	System Kayla Peay (b) (4)	12 Aug 2020 15:07:33 12 Aug 2020 15:06:48

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'seasonal allergies' reason for change:	Kayla Peay (b) (4)	13 Aug 2020 00:00:28
Data Entry Error	(b) (4)	
User entered 'medical history'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '50'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'ug (ug)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'as needed (PRN)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Nasal (NASAL)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:05:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 15:06:48
User entered 'un UNK 2017'	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 15:06:48

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	12 Aug 2020 15:06:48
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 15:06:48

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 15:06:48

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 15:06:48

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 00:09:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:09:54
Data point term sent to Coder	System	14 Aug 2020 20:00:21
User entered 'TYLENOL'	Amy Ford (b) (4) (b) (4)	14 Aug 2020 19:59:52

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'HEADACHE'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '325'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'mg (mg)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'as needed (PRN)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Oral (ORAL)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '9 Aug 2020'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Amy Ford (b) (4)	14 Aug 2020 19:59:52
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:59:52

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:59:52

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:59:52

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 05:23:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 05:23:36
Data point term sent to Coder	System	07 Apr 2021 18:01:07
User entered 'cephalexin'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'acute sinusitis'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '500'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'mg (mg)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'twice daily (BID)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '02 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered '09 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User entered '2'	System	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User entered '1'	System	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:09
User entered '804 (804)'	System	07 Apr 2021 18:00:27

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 09:40:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:40:37
Data point term sent to Coder	System	07 Apr 2021 18:01:08
User entered 'prednisone'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:01:05

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'covid like symptoms'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '20'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'once daily (QD)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '29 Mar 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:05
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:01:05

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:01:05

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 18:01:05

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 05:23:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:23:35
Data point term sent to Coder	System	07 Apr 2021 18:02:09
User entered 'cephalexin'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:01:37

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'covid like symptoms'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '500'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'twice daily (BID)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '29 Mar 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:01:37
	(b) (4)	

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Apr 2021 18:01:37

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:01:37

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 18:01:37

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:03:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:03:43
Data point term sent to Coder	System	07 Apr 2021 18:03:10
User entered 'acetaminophen'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered '650'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'as needed (PRN)'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered '26 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered '28 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:46
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User entered empty.	System	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User entered empty.	System	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:19
User entered empty.	System	07 Apr 2021 18:02:53

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:36:39
Data point term sent to Coder	System	07 Apr 2021 18:04:10
User entered 'cleocin'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'perirectal abscess'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered '600'	Marlee Smith (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'once (ONCE)'	Marlee Smith (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered '25 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered '0'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:40
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User entered empty.	System	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User entered empty.	System	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:21
User entered empty.	System	07 Apr 2021 18:03:44

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:36:39
Data point term sent to Coder	System	07 Apr 2021 18:05:13
User entered 'cleocin'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'perirectal abscess'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered '900'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'every 8 hours'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered '25 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered '28 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:37
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User entered empty.	System	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User entered empty.	System	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:23
User entered empty.	System	07 Apr 2021 18:04:33

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User closed query 'Per MM: Please provide a more specific medication name. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:28:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: OTHER SYSTEMIC HEMOSTATICS, PRODUCT: DESMOPRESSIN ACETATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 19:56:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 19:56:44
Query 'Per MM: Please provide a more specific medication name. ' answered with 'Exact med name added' (Site from DM).	Sara Poff (b) (4)	27 Apr 2021 16:49:44
Data point term sent to Coder	System	27 Apr 2021 16:49:15
DataPoint Un-verified.	Sara Poff (b) (4)	27 Apr 2021 16:49:11
Coding entries removed.	(b) (4)	27 Apr 2021 16:49:11
User entered 'desmopressin acetate (DDAVP, Stimat)' reason for change: Data Entry Error	Sara Poff (b) (4)	27 Apr 2021 16:49:11
User opened query 'Per MM: Please provide a more specific medication name. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 12:37:35
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: OTHER SYSTEMIC HEMOSTATICS, PRODUCT: DESMOPRESSIN ACETATE, PRODUCTSYNONYM: DDAVP - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 06:11:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	08 Apr 2021 06:11:09
Data point term sent to Coder	System	07 Apr 2021 18:06:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'DDVAP'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User closed query 'Per MM: Please review and confirm the indication.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:30:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
Query 'Per MM: Please review and confirm the indication.' answered with 'Correct per subject ' (Site from DM).	Sara Poff (b) (4)	27 Apr 2021 16:50:07
User opened query 'Per MM: Please review and confirm the indication.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 12:37:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered '47.16'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'ug (ug)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'once (ONCE)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered '28 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered '28 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:34
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User entered empty.	System	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User entered empty.	System	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:38
User entered empty.	System	07 Apr 2021 18:05:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User closed query 'Per MM: Please provide a more specific medication name. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:28:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: OTHER SYSTEMIC HEMOSTATICS, PRODUCT: DESMOPRESSIN ACETATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 19:56:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 19:56:44
Query 'Per MM: Please provide a more specific medication name. ' answered with 'Exact name of med given ' (Site from DM).	Sara Poff (b) (4)	27 Apr 2021 16:51:41
Data point term sent to Coder	System	27 Apr 2021 16:51:18
DataPoint Un-verified.	Sara Poff (b) (4)	27 Apr 2021 16:51:13
Coding entries removed.	(b) (4)	27 Apr 2021 16:51:13
User entered 'desmopressin acetate (DDAVP, Stimat)' reason for change: Data Entry Error	Sara Poff (b) (4)	27 Apr 2021 16:51:13
User opened query 'Per MM: Please provide a more specific medication name. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 12:37:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: OTHER SYSTEMIC HEMOSTATICS, PRODUCT: DESMOPRESSIN ACETATE, PRODUCTSYNONYM: DDAVP - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 06:11:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	08 Apr 2021 06:11:11
Data point term sent to Coder	System	07 Apr 2021 18:06:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'DDVAP'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User closed query 'Per MM: Please review and confirm the indication.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:30:38
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
Query 'Per MM: Please review and confirm the indication.' answered with 'Correct per subject ' (Site from DM).	Sara Poff (b) (4)	27 Apr 2021 16:52:09
User opened query 'Per MM: Please review and confirm the indication.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 12:38:08
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered '35.36'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'ug (ug)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'once (ONCE)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered '25 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:32
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User entered empty.	System	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User entered empty.	System	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:41
User entered empty.	System	07 Apr 2021 18:06:00

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:29
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:16:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:16:31
Data point term sent to Coder	System	07 Apr 2021 18:08:16
User entered 'diatrizoate meg-diatrizoate sod'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered '66-10'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'Other (OTHER)'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'Per cent'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'once (ONCE)'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered '25 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:29
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User entered empty.	System	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User entered empty.	System	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:43
User entered empty.	System	07 Apr 2021 18:07:16

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:37:47
Data point term sent to Coder	System	07 Apr 2021 18:08:16
User entered 'pepcid'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered '20'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'every 12 hours'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered '0'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered '28 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:27
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User entered empty.	System	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User entered empty.	System	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:48
User entered empty.	System	07 Apr 2021 18:08:08

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:24:46
Data point term sent to Coder	System	07 Apr 2021 18:09:17
User entered 'fentanyl citrate'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'perirectal abscess'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered '50'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'ug (ug)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'once (ONCE)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered '0'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered '25 Feb 2021'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:33:23
User entered 'No (N)'	Marlee Smith (b) (4)	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User entered empty.	System	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User entered empty.	System	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:34:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:21:50
User entered empty.	System	07 Apr 2021 18:08:50

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:34:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:41
User closed query 'Per CDM: Concomitant Procedures summary performed is No, however data is present on Concomitant Procedures eCRF. Please review and update accordingly.	(b) (4), (b) (6)	14 Apr 2021 06:38:48
' (Site from DM).		
Query 'Per CDM: Concomitant Procedures summary performed is No, however data is present on Concomitant Procedures eCRF. Please review and update accordingly.	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 13:32:23
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Apr 2021 13:32:07
User opened query 'Per CDM: Concomitant Procedures summary performed is No, however data is present on Concomitant Procedures eCRF. Please review and update accordingly.	(b) (4), (b) (6)	10 Apr 2021 14:11:50
' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 15:03:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 21:00:13
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 20:57:40

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:43

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:09:34
	(b) (4)	

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'incision and drainage of perirectal abscess'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:09:34

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:09:34

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:09:34

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:34:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:09:47

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:34:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'lithotomy'	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:09:47

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	07 Apr 2021 18:09:47

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:34:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:09:47

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:34:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered '25 Feb 2021'	Marlee Smith (b) (4)	07 Apr 2021 18:10:03

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:34:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'placement of seton'	Marlee Smith (b) (4)	07 Apr 2021 18:10:03

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:34:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	07 Apr 2021 18:10:03

US3722158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:34:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:31:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:31
User entered empty.	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 18:10:03

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '01/Mar/2021 15:11'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '02/Mar/2021 09:15'	System	02 Mar 2021 14:16:01

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 14:16:01

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '08/Mar/2021 12:32'	System	08 Mar 2021 17:33:00

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:53:14
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 17:33:00

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '16/Mar/2021 12:53'	System	16 Mar 2021 17:53:38

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 17:53:38

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '08/Apr/2021 10:35'	System	08 Apr 2021 14:35:35

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 14:35:35

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'USA-US083-2021-MRNA-1273-P301000012'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Yes (Y)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'No (N)'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Luis'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'De La Cruz'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '2 Roper Corners Cir'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'Greenville'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered 'SC'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:11:29
User entered '29615'	System	01 Mar 2021 20:03:05

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:32:41
User entered 'US'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:34:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:11:42
User entered '5'	System	08 Apr 2021 14:35:35
User entered '4'	System	16 Mar 2021 17:53:38
User entered '3'	System	08 Mar 2021 17:33:00
User entered '2'	System	02 Mar 2021 14:16:01
User entered '1'	System	01 Mar 2021 20:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:34:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered '09/Apr/2021 09:11'	System	09 Apr 2021 13:11:42

US3722158

Folder: SAE USA-US083-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:34:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:51:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:34:53
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:11:42